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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

Held in the Centre William Rappard
on 8-9 and 31 March 2005

Chairperson: Mr. Tony Miller (Hong Kong, China)

The present document contains the record of the discussion which took place during the TRIPS Council meeting held on 8-9 and 31 March 2005.

Subjects discussed — Page nos.

A. NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

1. The Chairman informed the Council that, since its meeting in December 2004, it had received a number of supplements and updates to earlier notifications of laws and regulations. Albania had updated the notification of its laws and regulations that was circulated in 2001; the Czech Republic had notified a law relating to border measures and certain amendments to its intellectual property legislation; Japan had provided an updated text of its Seeds and Seedlings Laws; and Jamaica had notified amendments to its copyright legislation and industrial property fees and a law concerning its accession to the Nairobi Treaty on the Protection of the Olympic Symbol. These notifications were being circulated in the IP/N/1/- series of documents. He urged those Members whose initial notifications remained incomplete to submit the outstanding material without delay, and reminded other Members of their obligation to notify any subsequent amendments of their laws and regulations without delay after their entry into force.

2. As regards notifications of contact points under Article 69, he said that, since the Council's meeting in December, updates to contact points notified earlier had been received from Albania, the Slovak Republic and the United States. These notifications had been circulated in document IP/N/3/Rev.8/Add.2. There were now 121 Members who had notified contact points under Article 69.

3. The Council took note of the information provided.

B. FOLLOW-UP TO REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

4. The Chairman said that the Secretariat had updated its informal note that listed the outstanding material required to complete the reviews that the Council had already undertaken (JOB(05)/27). The table attached to the note listed 14 Members whose reviews had been initiated at the Council's meeting since April 2001 but which remained on the Council's agenda. The table referred to submissions, including both responses and follow-up questions, received by 2 March 2005. As requested by the Council at its last meeting, the Secretariat had written to these Members, drawing their attention to the outstanding material required to complete the pending reviews.

5. Since the Council's last meeting, Armenia had provided responses to the last outstanding questions posed to it (IP/C/W/422/Add.1). The Chairman suggested that the regular review of the legislation of Armenia be deleted from the agenda, it being understood that any delegation could revert to any matter stemming from this review at any time.

6. The Council so agreed.

7. The Chairman turned to the remaining 13 Members, namely Congo; Cuba; Egypt; Fiji; the Former Yugoslav Republic of Macedonia; Grenada; Mauritius; Qatar; Saint Kitts and Nevis; Saint Vincent and the Grenadines; Suriname; Swaziland; and Zimbabwe.

8. The representative of Egypt said that she was coordinating with her capital and hoped to be able to provide further information in the near future.

9. The representative of Zimbabwe said that his delegation would provide the outstanding responses in the near future.

10. The Chairman said that the Secretariat note also listed five Members whose reviews had already been deleted from the Council's agenda on the understanding that any delegation should feel free to revert to any matter stemming from the review at any time. In that connection, certain questions had been raised with regard to the implementing legislation of those countries. Since the

circulation of the note, Argentina had provided responses to all of the remaining follow-up questions posed to it by Switzerland (IP/Q/ARG/1/Add.2).

11. The representative of Switzerland thanked the delegation of Argentina for its responses and said that he would send them back to the capital for further study.

12. The Chairman 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 those reviews. He suggested that the Council revert to this matter at its next meeting.

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

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[1]

14. The Chairman recalled that, at the end of the discussion of the three agenda items at the Council's December meeting, he had observed that there had been useful discussions, and that there were several constructive contributions, including suggestions and counter suggestions for a more structured discussion on some of the issues and approaches. Since then, he had continued his consultations on how future work on these items should be organized. His impression was that there was a wide view that the discussions presently taking place were both fruitful and constructive and were enabling all points of view to be put forward and explored. Thus, he did not see any need to propose any new way to organize work on these matters, and suggested that Members continue to discuss the three agenda items together on the basis of contributions by Members.

15. He recalled that, at its meeting in September 2004, the Council had received a submission from Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela on "Elements of the Obligation to Disclose the Source and Country of Origin of Biological Resource and/or Traditional Knowledge Used in an Invention" (IP/C/W/429/Rev.1 and add.1). Since the Council's meeting in December, Colombia and the Dominican Republic had requested that they be added to the list of sponsors of the submission (IP/C/W/429/Rev.1/Add.2 and 3). In addition, three new documents had been presented at the December meeting, one from Switzerland (IP/C/W/433), another from the United States (IP/C/W/434), and the third from Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela (IP/C/W/438). At that meeting, some delegations had said that they intended to comment on these submissions at the present meeting. Since the December meeting, the Council had received the following new communications: one from Peru (subsequently circulated as IP/C/W/441); another from Brazil on behalf of Bolivia, Brazil, Colombia, Cuba, the Dominican Republic, Ecuador, India, Peru and Thailand (subsequently circulated as IP/C/W/442); and a third from India on behalf of Brazil and India (IP/C/W/443).

16. The representative of Peru, introducing document IP/C/W/441, said that his delegation was committed to the discussion of the disclosure issue in the WTO, which, in its view, was the appropriate forum for this. He said that it was time for Members to stop "forum shopping" and commit themselves to finding concrete solutions to the problems of misappropriation of genetic resources and biopiracy. He reiterated that due priority should be given to the disclosure issue within

[1] As requested by the delegations of Peru, Turkey and India and agreed by the Council, the record also reflects the statements made by these delegations during an informal meeting on TRIPS matters that the Chairman of the Council held, acting as a Friend of the Director-General, on 8 March 2005.

the rubric of outstanding implementation issues as it had reached sufficient maturity to enable concrete negotiations to begin in order to arrive at a favourable solution for developing countries by the end of the current round. His delegation wished this issue to be included in the negotiations for the Ministerial Conference in Hong Kong, China, as the current round could not otherwise be called a development round.

17. The objective of the Peruvian submission was to present the problems faced by a developing country in the fight against biopiracy and to illustrate the efforts necessary to be made in the absence of a universal and legally-binding obligation to disclose origin of genetic resources related to a patent. As the Council was already aware, Law 28216 of 1 May 2004 had established the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (hereinafter the National Anti-biopiracy Commission). This Commission was chaired and coordinated by the National Institute for the Defence of Competition and Intellectual Property Protection (INDECOPI) and was made up of the representatives of the Ministry of Foreign Relations, Ministry of Foreign Trade and Tourism (MINCETUR), National Environmental Council (CONAM), Commission for the Promotion of Exports (PROMPEX), National Institute for Natural Resources (INRENA), National Institute for Agricultural Research and Extension (INIEA), International Potato Centre (CIP), National Centre for Intercultural Health (CENSI), National Commission of Andean, Amazonian and Afro-Peruvian Peoples (CONAPA), National Assembly of Governors (ANR), Peruvian Environmental Law Society (SPDA) (representing the NGOs), and the Peruvian Institute for Natural Products (IPPN) (representing business associations).

18. The National Anti-Biopiracy Commission had the task of developing actions to identify, prevent and avoid acts of biopiracy with an aim to protect the interests of the Peruvian State. Its main functions were to establish and maintain a register of biological resources and traditional knowledge; provide protection against acts of biopiracy; identify and follow up patent applications made or patents granted abroad that relate to Peruvian biological resources or collective knowledge of the indigenous peoples of Peru; make technical evaluations of the above-mentioned applications and patent grants; issue reports on the cases studied; lodge objections or institute actions for annulment concerning the above-mentioned patent applications or patent grants; establish information channels with the main intellectual property offices around the world; and draw up proposals for the defence of Peru's interests in different forums.

19. The National Anti-Biopiracy Commission had considered it desirable to share the experience acquired in this first stage of the search for potential cases of biopiracy, in as much as this may contribute to an understanding of the problems faced by a country like Peru in the fight against biopiracy. To that end, and in order to enrich the ongoing debate within the TRIPS Council concerning the disclosure requirement, the results of a search effected on the websites of the main patent offices in the world, namely, the United States, Europe and Japan, were presented in respect of six priority resources of Peruvian origin, together with a summary of the patent documents found wherein the inventions claimed related to those resources, and which might involve the use of traditional knowledge of the indigenous peoples of Peru. The products presented in the submission were: *hercampuri, camu-camu, yacón, caigua, sacha inchi* and *chancapiedra*. However, these six products were just a sample of more than fifty products of vegetal and animal origin, which the National Anti-Biopiracy Commission had already started to investigate since their medicinal properties were being analysed and tested in several countries.

20. This document was the fruit of the efforts carried out by the National Anti-Biopiracy Commission to identify possible cases of biopiracy as the subject-matter of a more rigorous and detailed analysis and of possible administrative or judicial proceedings. It was no more than the first step in the long and complex process starting with the search for potential cases of biopiracy and ending with the institution of actions against pending patent applications or patents obtained or developed from the use of a biological resource or traditional knowledge without the prior informed

consent of the country of origin of the resource or of the indigenous people owning rights in the knowledge, and without providing for any type of compensation to that country or indigenous people.

21. He hoped that this document would help serve the purpose of: (a) ascertaining how a mega-diverse country makes a serious attempt to address this phenomenon through its institutions; (b) understanding to some extent the methodology and standards used in the search for such patents, thereby helping other countries or regions which might wish to initiate similar efforts; (c) gaining knowledge of the large number of inventions referring to resources of Peruvian origin that might reflect cases of biopiracy (either because such resources have been obtained illegally, or because they involve the unauthorized use, without compensation, of traditional knowledge); and (d) demonstrating that a systematic and methodical search and analysis of "problem" patents can be undertaken.

22. He stressed that no assertion was being made that all the pending patent applications or patent grants mentioned in the attached report did not deserve protection. What was presented was merely a set of pending patent applications or patent grants which had as their subject matter inventions apparently obtained or developed using biological resources of Peruvian origin and/or traditional knowledge of the indigenous peoples of Peru, for which it was necessary to check whether the rights of Peru as the country of origin of the resources and of the indigenous peoples of Peru as the owners of rights in the knowledge had been respected.

23. He said that Peru had had to make significant efforts, both in terms of human and material resources, in order to fight against biopiracy. This was why it was necessary to require the disclosure of origin in patent applications to fight biopiracy. Upon the conclusion of the Uruguay Round, countries had made a commitment to implement new standards for the promotion and protection of intellectual property rights. Since then, Peru, like many other developing countries, had made enormous efforts to fight against piracy and enforce intellectual property rights in its territory. He said that the time had come to take a concrete decision to include the disclosure issue in the negotiations on implementation issues in order to present results by July 2005 and the next Ministerial Conference in order to find a solution by the end of the Development Round. He said that Peru considered the TRIPS Council, and the WTO in general, to be the appropriate forum to discuss this issue, because of the legally-binding nature of its agreements. He shared India's view with respect to the necessity to hold dedicated consultations on the issues related to disclosure of origin.

24. The representative of Brazil introduced the submission made by Bolivia, Brazil, Colombia, the Dominican Republic, Ecuador, India, Peru and Thailand on the "Elements of the Obligation to Disclose Evidence of Benefit Sharing under the Relevant National Regime" (IP/C/W/442). He recalled the previous submissions made by the proponents from the TRIPS Council meeting of March 2004 onwards, including the Checklist, which he said had been generally accepted as the basis for pursuing discussions on this issue. The new submission addressed and elaborated the third and final set of issues mentioned in the Checklist, namely the disclosure of evidence of benefit-sharing under the relevant national regime and should be read together with the earlier submissions, as the elements treated therein were closely interlinked.

25. He said that the first section of the new document sought to explain what was meant by evidence of benefit-sharing under the relevant national regime. The disclosure requirement was aimed at ensuring not only that there was benefit-sharing *per se*, but that such benefit-sharing took place in a fair and equitable manner, taking into account the circumstances of each particular case. It had been argued that there might be no straightforward way of determining the fair and equitable sharing of benefits. There were a number of factors that could be used to make this determination such as, in the case where there had been sufficient prior informed consent, that the shaping of benefits or an arrangement for future sharing of benefits was premised upon mutually agreed terms in the context of Article 15(7) of the CBD. Also, consideration should be given to whether there was a

reporting obligation on issues relating to patenting or commercialization, especially where future benefit-sharing was contemplated.

26. Some had argued that a disclosure requirement for benefit-sharing, as well as related disclosure requirements for country of origin and prior informed consent, could not *per se* transfer benefits and that national level mechanisms for benefit-sharing must be established. He said that the disclosure proposal was not intended as a replacement for national access and benefit-sharing regimes but as supplementary measures and necessary incentives for patent applicants to comply with the prevalent laws and practices of the countries of origin of the genetic resources and/or associated traditional knowledge. Thus, bio-prospectors, researchers and other prospective patent applicants who wished to access genetic resources and associated traditional knowledge in a fully lawful manner had nothing to fear from the proposed disclosure requirements as these would do little other than to ask applicants to supply information to the effect that the resources and knowledge had been accessed lawfully in the countries of origin. There was no reason why such requirements should be found cumbersome by well-meaning patent applicants.

27. He emphasized that "biopiracy" was a global problem, more often than not involving the acquisition of material in one country and the seeking of a patent over that material, or over inventions deriving from or involving that material, in another country. Therefore, to effectively tackle the problem, it would not be sufficient to rely solely on measures and regimes adopted at the national level in the countries of origin of the genetic resources and an international framework of protection was needed. The ability of patent offices and other authorities in a national jurisdiction to curb biopiracy by imposing a disclosure requirement would be limited unless similar actions were also taken by patent offices in other jurisdictions. Disclosure of evidence of benefit-sharing, as well as the disclosure of the country of origin and of evidence of prior informed consent, would enhance the credibility of the patent system by contributing to the realization of the stated objectives and principles of the TRIPS Agreement itself, as enshrined in Articles 7 and 8.

28. Questions had been asked about when the patent applicants would be expected to introduce evidence of benefit-sharing. Some had pointed out that benefit-sharing can only take place after the grant of a patent and the commercialization of the relevant technology. This did not raise a problem with respect to furnishing the evidence of benefit-sharing. In many cases, the very fact of gaining access to genetic resources might trigger a certain level of benefit-sharing. When real benefits could only arise from the patenting and commercialization of the invention, it was still envisaged that the patent applicant would be required to provide evidence of benefit-sharing. The applicant could do so by submitting evidence of the existence of an arrangement for the fair and equitable sharing of benefits arising out of the utilization of the genetic resources, an arrangement that would have been entered into in accordance with the national laws and practices of the country of origin.

29. If there was no national regime in the country of origin, then a similar approach to that taken for prior informed consent, as specified in document IP/C/W/438, would apply. The applicant would merely have to indicate in the relevant declaration that there had been no national access and benefit-sharing regime in the country of origin, but that, in any case, benefit-sharing had or would take place through an arrangement established with the authorities in charge of the location where the resources were accessed.

30. The final section of the new document addressed the question of the legal effects of non-compliance with the requirement to disclose evidence of benefit-sharing. As in the case of the obligation to disclose evidence of prior informed consent, the nature of the legal effects of non-compliance with disclosure of benefit-sharing would depend on whether it is at pre- or post-grant stage. At the pre-grant stage, if no evidence of benefit-sharing was furnished as required before the examination or grant of the patent, then the legal effect could be that the application is not processed any further until the necessary evidence is submitted. This could be accompanied by penalties and

time-limits within which the proper declaration and evidence must be provided. Where failure to disclose evidence of benefit-sharing was discovered after the grant of the patent, the legal effects could include revocation of the patent, particularly where it was determined that there was a fraudulent intention behind the failure to provide evidence of benefit-sharing. It could also include full or partial transfer of rights to the invention as a means to promoting fair and equitable benefit-sharing or criminal and/or civil penalties, including the possibility of punitive damages, where it was determined that the patent holder had, in fact, provided benefits but had not provided the evidence in the application.

31. Speaking on behalf of his delegation, he said that Brazil shared the concerns raised by Peru and had faced similar problems. In recent times, a number of similar cases involving resources and/or knowledge which had been taken from the Brazilian Amazon had been also brought to the attention of the authorities. Those were apparent cases of misappropriation involving attempts to take out patent rights over resources and/or traditional knowledge of the Amazon and the indigenous peoples residing in this region, involving a number of important biological materials that are well-known to the Brazilian population. There had been an attempt to steal the name of a well-known fruit and to have it registered as a trademark in the big markets of the North. There was also a very recent case involving the extraction of a substance from the skin of a frog from the Amazon and apparently there had been attempts to take out patent rights over the extracted substances and also involving traditional knowledge used by indigenous peoples in Brazil. These cases were being investigated by the Brazilian authorities.

32. It was clear that the current intellectual property system was inadequate to address the biopiracy problems faced by developing countries. The system was inequitable, since it facilitated the actions of powerful, industrial interests, but there were no safeguards to protect the rights of developing countries and their indigenous communities. This imbalance would be rectified with an amendment to the TRIPS Agreement, including the disclosure of origin obligation. Like the delegation of Peru, Brazil called upon WTO Members to engage constructively in the light of the mandate given by the Ministers and to refrain from engaging in "forum shopping".

33. The representative of India said that the paper presented by the delegation of Peru responded to the view of some Members that national experiences could help them in working towards an outcome on the issue of disclosure. He said that further substantive discussions on the issue of disclosure were necessary. The Peruvian experience of establishing the National Anti-Biopiracy Commission showed that national efforts were not enough to prevent biopiracy and that an international mandatory obligation to introduce disclosure requirements in patent applications was necessary. He supported the statement made by Brazil, in its presentation of document IP/C/W/442 co-sponsored also by India, confirming the existence of biopiracy and looked forward to the views of Members on the contents of the submission.

34. Introducing document IP/C/W/443 on behalf of Brazil and India, he recalled that the United States had submitted document IP/C/W/434 during the last TRIPS Council meeting in which it had said that it viewed with utmost caution any proposals that would add uncertainties to patent rights, or undermine the role of the delicately balanced patent system. He said that the disclosure requirements in the joint proposal by India and other Members had, on the other hand, introduced certainty for researchers and bio-prospectors. It would ensure the legitimacy of the patent system and preserve and strengthen its balance. Document IP/C/W/434 had argued that new patent disclosure requirements would not work to guarantee that prior informed consent was obtained, and suggested an approach based on national level contractual arrangements. The co-sponsors of IP/C/W/443 were in agreement with the United States that national level laws were an important component in order to address the relevant goals, but have said that these were not enough. Just as national level patent regimes alone did not suffice and TRIPS Agreement had been introduced in the WTO to address that insufficiency,

national level contractual arrangements could only suffice if they were obligatory and enforceable across borders.

35. He said that there was a significant international dimension of mutual supportiveness of the CBD and the TRIPS Agreement. On the one hand, Article 5 of the CBD envisaged international cooperation with competent international organizations. On the other hand, the WTO was competent with regard to international minimum standards for patents based on biological resources and/or traditional knowledge and thus, with regard to cross-border biopiracy and misappropriation. It was argued in IP/C/W/434 that the act of patenting *per se* did not constitute misappropriation. The co-sponsors of document IP/C/W/443 agreed and had said that what constituted a misappropriation was the act of applying for a patent or patenting an invention using biological resources and/or traditional knowledge without obtaining prior informal consent and sharing benefits. The disclosure proposal remedied such form of misappropriation. The document had also argued that the disclosure requirement *per se* could not transfer benefits, since it would merely convey the information required but would have no mechanism to transfer benefits. However, the proposed disclosure of the use of biological material or traditional knowledge and evidence of prior informed consent and benefit-sharing arrangements, coupled with the national level regimes on prior informed consent and ABS would ensure the transfer of benefits.

36. Further, IP/C/W/434 argued that benefits from an invention would be diminished if patents were not issued, or revoked, and yet inventions were commercialized. However, this phenomenon was not limited to patents related to biological material and could happen to any invention. As in any other case, other legal means would have to be used to rectify the damage, such as parallel importation

37. He said that the submission from the United States had argued that the disclosure requirements would be ineffective in preventing erroneously granted patents, and did little to ascertain inventorship, novelty or inventive step. However, the disclosure requirement would ensure that information is disclosed on whether biological resources and/or traditional knowledge had been used; (a) to form part of the claimed invention, (b) in developing the invention, (c) as its necessary pre-requisite, (d) in facilitating the invention, or (e) as its necessary background material or information. Such information would be relevant in determining prior art, non-obviousness and inventorship or entitlement to a patent. IP/C/W/434 accepted this premise when it refers to the benefits of organized searchable databases.

38. He recalled that document IP/C/W/434 had raised concerns on administrative burdens and costs and on the capacity of patent examiners to determine the validity of prior informed consent or adequate benefit-sharing. The issue of administrative burdens and costs had been addressed in document IP/C/W/429/Rev. l. In terms of implementation for the US system, the proposed disclosure requirement would not be burdensome at all, as it could be covered under the existing requirement of information material to patentability. What would need to be included was evidence of prior informed consent and benefit-sharing arrangements. The proposal did not require patent examiners to determine the validity of these arrangements in order to grant a patent.

39. Furthermore, IP/C/W/434 had proposed an alternative mechanism outside the patent system. But a fragmented nation-to-nation system would not achieve the objectives and would imply high transaction costs. National-level requirements could do little to address the transnational character of biopiracy. Organized searchable databases were useful to determine prior art but were complementary to and could not substitute for the disclosure requirement. He said that the explanations contained in the paper presented by his delegation should persuade all Members of the benefits of the disclosure requirement and the conclusion that there was no further alternative.

40. Speaking on behalf of India, he referred to the earlier papers that had been co-sponsored by his delegation, and said that they sought to address the mandate contained in paragraph 12 and 19 of the Doha Ministerial Declaration and the realization of a key development dimension, guided by the principles and objectives of the TRIPS Agreement as set out in Articles 7 and 8, and responded to the need for an outcome as part of the conclusion of the work programme set out in the Doha Ministerial Declaration.

41. The representative of Cuba associated her delegation with document IP/C/W/442. The document was explicit and developed the viewpoints of the competent authorities in Cuba with regard to the need to modify the TRIPS Agreement. The amendment was necessary to achieve a balance between patent holders worldwide and the holders of traditional knowledge associated to genetic resources. It was necessary to make patent rules compatible with the TRIPS Agreement and the CBD, based on multilateral reciprocity, so that the interests of both groups of holders were adequately balanced.

42. The representative of the United States recalled that the United States saw no conflict between the TRIPS Agreement and the CBD. Both agreements could be implemented in a mutually supportive manner and there was no need for an amendment to the TRIPS Agreement. The CBD did not require patent disclosure requirements; it only called upon parties to condition access to genetic resources on prior informed consent and to encourage the equitable sharing of benefits arising upon mutually agreed terms.

43. The most effective means to achieve the objectives of authorized access to genetic resources and the equitable sharing of benefits was through tailored national solutions. New patent disclosure requirements would add uncertainties into the patent system and open a new avenue for litigation and dispute. This would undermine the role of the patent system in promoting innovation and technological development and the economic incentives that patents provide and any potential benefit-sharing that would be derived therefrom.

44. She believed that there was a growing recognition that the new patent disclosure requirements were not enough to guarantee that prior informed consent had been obtained and that benefits were shared in a fair and equitable way. It was obtaining authorized access and not the disclosure of origin in a patent application that manifested prior informed consent. Fair and equitable benefit-sharing was accomplished upon an agreement by entities. The contract-based system was easily adaptable to a country's particular legal system and provided the flexibility to protect traditional knowledge and genetic resources without undermining the economic development incentives of strong intellectual property protection. The proposed patent disclosure requirements would not be effective in preventing erroneously granted patents.

45. Responding to the Peruvian submission, she said that Peru had cited a number of pending published patent applications but, since the patentability of the claimed inventions had not been determined, it would be improper to comment on those. It was not clear whether the mere filing of a patent application could amount to an act of misappropriation. Peru had also discussed the patent applications relating to *Maca* during the introduction of its paper. Her delegation had reviewed the data base of US patents and located some patents related to *Maca*, citing literature dating to the 1960's and all the patents had disclosed the country of origin as Peru. Apparently, the inventors had created new, useful and non-obvious inventions from the genetic material that fully met the patenting criteria under US patent law, for example patents pertaining to chemically active isolates, chemical compounds and compositions and not the plant itself. This did not appear to be an example of misappropriation. Her delegation had also reviewed the patents related to the *Chancapiedra* that Peru had referred to in its paper. They covered novel compositions useful in cosmetics, and that met the statutory requirements for patentability. They listed more than thirty species of plants from which the

active ingredients might be derived and that were available from sources throughout the world. They had not identified any examples of misappropriation or biopiracy.

46. She recalled that while some delegations had recognized that contract-based access and benefit-sharing systems were essential, others had continued to argue that patent disclosure requirements were needed to improve compliance with such mechanisms. The United States disagreed with such a policy approach as it was burdensome for the patent system and did not effectively meet the stated goals. Effective enforcement regimes for access and benefit-sharing would be part of civil and criminal codes and might include existing established mechanisms to enforce contracts.

47. She was pleased that the Indian delegation agreed that patenting in itself did not constitute misappropriation. Patents could, in combination with an effective access and benefit-sharing regime, be a valuable tool to generate benefits that could later be shared. If new patent disclosure requirements were adopted and non-compliance was discovered that would invalidate a patent, any benefits from that invention would be greatly diminished.

48. Patent laws were designed to promote the progress of the useful arts by awarding intellectual property rights. They were not designed to regulate all matters relating to those inventions. Restrictions were placed on the use of certain inventions to ensure safety and efficacy, for example the health regulations governing pharmaceuticals, environmental regulations on emissions from automotive engines, or to protect domestic and national security, such as the regulations on firearms. These restrictions were implemented and enforced outside the patent system. The patent system did not condone violation of these other laws and in the same manner, the patent system did not condone misappropriation of genetic resources and violation of a country's access and benefit-sharing requirements. Just as health, safety and environmental regulations applied in their own spheres, a contract-based administrative access and benefit-sharing system could effectively and adequately achieve domestic policy goals related to the conservation and sustainable use of genetic resources. Criminal and civil liability for failure to comply with an access and benefit-sharing system requirement could be included in a country's laws. She said that Members should fully examine national experiences with respect to access and benefit-sharing systems currently in place in order to better understand the perceived shortcomings of such existing systems. The Council might also want to consider the work of the IGC on Intellectual Property, Genetic Resources and Folklore at the WIPO.

49. The representative of Ecuador said that the delegation of Peru had, in its presentation of document IP/C/W/441, explained clearly the difficulties faced due to the lack of international rules and provided elements on the importance of protecting genetic resources and traditional knowledge. There was a need to amend the TRIPS Agreement to include the disclosure of origin and source in the requirements for patentability. He said that document IP/C/W/442, presented by Brazil and co-sponsored by his delegation, put forward concepts to demonstrate the validity of the arguments on the relationship between the TRIPS Agreement and the CBD. His delegation had always expressed their position in favour of the obligation to disclose the source and origin of genetic resources. He said that it was important to take into account the arguments that had been presented in document IP/C/W/443. The issues presented in this document did not burden the intellectual property system and responded to the need for a balance in the TRIPS Agreement. Instead of creating uncertainty or undermining the international patent system, the incorporation of the disclosure requirement would enhance legal certainty and predictability and strengthen the legitimacy of the patent grant. It was important to agree on this minimum set of international rules to strengthen the intellectual property system.

50. The representative of Indonesia supported the document that had been introduced by Brazil (IP/C/W/442). This submission was a constructive contribution in the efforts to find a satisfactory solution, as mandated by the Ministers in the Doha Declaration. One of the core objectives of the

TRIPS agreement was to achieve a balance between rights and obligations and to ensure that the agreement is conducive to social and economic welfare. Indonesia implemented the TRIPS Agreement believing that its various provisions, would safeguard in totality the objectives and principles. However, as proved by the issue of access to medicines and recognized by the Members through the TRIPS and Public Health Declaration, the TRIPS Agreement had not fully met the objectives and principles which were enshrined in Articles 7 and 8. The lack of recognition under the TRIPS Agreement of the disclosure issue undermined the objectives and principles of the Agreement. Moreover, whilst the rights of new inventions were protected, many developing countries continued to lose out as resources and knowledge passed down form generations were exploited in these inventions.

51. He noted that some Members thought that the TRIPS Agreement did not present an obstacle to address the disclosure issue at the national context. He shared the view that the ability of patent offices and other authorities in a national jurisdiction to enforce prior informed consent and benefit-sharing mechanism in one jurisdiction, did not lead to similar actions in respect to patent applications in other countries. He agreed with the need to establish an international framework for disclosure and prior informed consent, as well as for access and benefit-sharing of genetic resources and traditional knowledge. The mandate on this issue clearly required the TRIPS Council to find a satisfactory solution. A balanced outcome of the negotiations was needed to ensure that issues of real concern for developing countries were addressed in this round.

52. The representative of New Zealand welcomed the deepening of the debate on this aspect of the work of the TRIPS Council. Her delegation had not yet made definitive decisions about disclosure in the national context, but had previously stated that disclosure in some form might assist or support CBD objectives. She agreed that there might be potential for measures such as disclosure of the source of genetic resources and associated traditional knowledge to further the objectives in the TRIPS Agreement as enunciated in Articles 7, 8 and 27. Additionally, such disclosure might bolster the TRIPS Agreement by providing more information to enable better decisions on the existing criteria for patentability.

53. She said that the two recently submitted papers acknowledged the primary role of national systems in ensuring prior informed consent in relation to access and benefit-sharing. The answers to problems of non-compliance with prior informed consent and benefit sharing were not to be found in the intellectual property system, but should be addressed primarily through national ABS systems, which had been comprehensively implemented only in a few countries. Without national systems being in place, the intellectual property system could not even play a supportive role. Any suggestion that an applicant should provide evidence of benefit-sharing through the intellectual property system where there had been no such requirement in the country of origin of the genetic resources, as suggested in paragraph 11 of document IP/C/W/442, went too far.

54. There was also a need to be realistic about the likely compensatory outcomes from this kind of disclosure that had been proposed, given that the majority of genetic-resource based research was non-commercial and even where bio-discovery was undertaken with commercial objectives in mind, the hit rate was very low. Her delegation was a little concerned that both sides seem to over-estimate the likely "green gold" at the end of the rainbow, and the potential benefits from patenting of inventions based on genetic resources. She was interested in following up on a Canadian proposal made at the last meeting and hearing further from proponents about how the disclosure system would work in practice, and how it might have been applied in some frequently cited examples of misappropriation.

55. The representative of Australia noted the large amount of work that had been generated on this issue not only in the TRIPS Council, but also in the WIPO. She said that there was no conflict between the TRIPS Agreement and the CBD and that the two agreements could be implemented in a

mutually supportive manner. Her delegation considered all the contributions as useful and that no particular document was the basis for the ongoing work. She said that the relationship between the problem of biopiracy and the solution proposed in documents such as IP/C/W/442 was still unclear. She agreed that the equitable sharing of benefits from the use of genetic resources and/or traditional knowledge was important and that the patent system was not the only solution to this problem. She was concerned about the possible effects of denying or invalidating patent protection because of a lack of a benefit-sharing arrangement. This might have the effect of undercutting the objectives of any benefit-sharing arrangement, if as a result of such action there was no way to capture the benefits of the innovation. She was also concerned about costs since this was not a simple notification system and would impose additional burdens on patent applicants and patent authorities. Paragraph 5 of document IP/C/W/429 stated that patent challenges involved high costs in terms of time and resources. She questioned how this system could be implemented while avoiding substantial costs, particularly with regard to the effects of non-compliance outlined in paragraph 14 of the new document relating to patent challenges.

56. The representative of Thailand said that his delegation attached great importance to the disclosure issue, as well as to GIs and the other implementation related issues. Contractual arrangements, as had been proposed in the previous meetings of the TRIPS Council, could not, in his view, solve the problem of biopiracy, nor did they safeguard genetic resources from being exploited outside the country of origin. The recent submissions explained in detail the disclosure issue. He said that the disclosure issue should not be dealt with only in the WTO, but also in other fora such as the WIPO and UNCTAD. The exercise at the WTO was to find a solution to this problem, as mandated by the Ministers at Doha.

57. The representative from China supported the submissions contained in documents IP/C/W/442 and IP/C/W/443. The proposals had provided specific suggestions on how to implement the obligation of submitting evidence of benefit-sharing and this would push forward the negotiations in order to build a reasonable international system on biotechnology. It was necessary to amend the TRIPS Agreement and other relevant international rules in accordance with the CBD. Each Member should prepare its laws to protect traditional knowledge and biodiversity. Regarding the United States proposal contained in document IP/C/W/434, he acknowledged that, to some extent, the contractual system was reasonable. However, it might lead to unfair results since developed countries might take advantage of their strong position on technology to force developing countries to accept an unfair contract.

58. The representative of the European Communities said that the Peruvian contribution on national experiences was very useful to better understand the issue. He said that, at the December meeting, his delegation had indicated that it would submit a proposal to WIPO on "Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications". This proposal had been sent to WIPO in the context of the invitation of the WIPO Director-General to submit proposals before 15 December in order to prepare a contribution to the Secretariat of the Convention on Biological Diversity. The objective of the EC proposal was to formulate a way forward that should ensure an effective, balanced and realistic system for disclosure in patent applications. The outline of the EU proposal was as follows: (1) a mandatory requirement should be introduced to disclose the country of origin or source of genetic resources in patent applications; (2) the requirement should apply to all international, regional and national patent applications at the earliest stage possible; (3) the applicant should declare the country of origin or, if unknown, the source of the specific genetic resource to which the inventor had had physical access and which was still known to him; (4) the invention must be directly based on the specific genetic resources; (5) there could also be a requirement on the applicant to declare the specific source of traditional knowledge associated with genetic resources, if he was aware that the invention was directly based on such traditional knowledge and, in this context, a further in-depth discussion of the concept of "traditional knowledge" was necessary; (6) if the patent applicant failed or refused to

declare the required information, and despite being given the opportunity to remedy that omission continued to do so, then the application should not be further processed; (7) if the information provided was incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law; (8) a simple notification procedure should be introduced to be followed by the patent offices every time they received a declaration and it would be adequate to identify in particular the Clearing House Mechanism of the CBD as the central body to which the patent offices should send the available information.

59. Commenting on document IP/C/W/438, he said that a disclosure of origin requirement was sufficient at this stage. There were serious problems with the introduction of a system where patent applicants should provide evidence of prior informed consent since it would impose an unreasonable burden on them. He sought clarification on the role that patent offices should play in such a system. In the view of his delegation, the request to verify whether patent applicants complied with legal rules related to the material used in their invention would overburden patent offices and create problems of legal interpretation.

60. With regard to the question of how furnishing evidence of prior informed consent would facilitate achieving the objectives of the CBD and ensure a harmonious relationship between the CBD and the TRIPS Agreement, and whether contractual arrangements could suffice to achieve the objectives of the CBD, his delegation took the view that the implementation of the CBD required a combination of legislative and/or regulatory approaches, setting the general rules, and of contractual approaches. Regarding the question of how the evidence of prior informed consent should be provided, he felt there was some incoherence between "requiring, as a condition for acquiring patent rights, that applicants furnish evidence of prior informed consent" (paragraph 8) and "requiring applicants to provide information known to them or which they should reasonably know" (paragraph 9) and sought a clarification of this point.

61. As to the nature of the obligation that should satisfy the requirement of prior informed consent, the developing country paper said that the declaration indicating that prior informed consent was obtained from the relevant national authorities would be accompanied, for example, by a certificate or duly certified contract between the applicant and the national authorities of the country of origin. The creation of an internationally recognised certificate of origin could certainly be a good idea, but was not relevant at this stage. In this respect, he would like to draw the attention of the Council to the recommendation adopted by the 3rd meeting of the CBD Ad Hoc Open-Ended Working Group on ABS that had been held in Bangkok on 14-18 February 2005, which had called for further studies and pilot projects as well as for views on the creation of a certificate of origin/source/legal provenance, scheduled to be discussed at the next ABS meeting in March 2006 in Spain.

62. As to what the obligation should be if there was no national regime in the country of origin, he said that in many countries such national regimes did not exist or, where they did, they were not fully operational. In these countries, certificates of evidence could not be delivered. This was one of the reasons why his delegation thought it was premature to consider a requirement to provide evidence of prior informed consent. As regards the legal effect of not providing evidence of prior informed consent, his delegation was not in favour of sanctions that would include the revocation of the patent.

63. The representative of Turkey said that all implementation issues had an equal footing. He shared the concerns voiced by Peru, India, Brazil and other developing countries and wanted to further discuss this issue in order to find an appropriate solution to the global biopiracy problem since the international system was insufficient to tackle this problem. A new mechanism should be included in the TRIPS Agreement in order to support the objectives and the adequate implementation of the CBD. His delegation was in favour of a patent system that would take into account the principles of prior informed consent and benefit-sharing in patent applications, so as to better protect

genetic resources and traditional knowledge. His country was trying to reflect these principles in its legislation and supported the proposals made by Brazil and India on the disclosure issue.

64. The representative of Norway said that Norway was in the process of reviewing its policy and hoped to promote the objectives of the CBD through the international patent system. Her delegation saw nothing in the TRIPS Agreement that prevented a Member from requiring patent applicants to disclose the source or origin of biological materials. For reasons of transparency, a provision that required or enabled Members to oblige a patent applicant to provide such information could be considered as it would enhance the support of the provisions of the CBD, particularly on equitable sharing of benefits and prior informed consent.

65. She recalled that Norway had amended its patent act in order to take into account the provisions of the CBD. Under the new provisions, patent applications concerning biological material should include information regarding the country of origin of the material. Also, should the national legislation of the providing country so require, information about whether prior informed consent had been given, should be submitted. These provisions did not apply to international patent applications. The duty to provide information was without prejudice to the processing of the patent applications. Nevertheless, a failure to provide correct information was liable to a penalty, under the general civil penal code. Her delegation viewed positively the recent proposal made by the European Communities to the WIPO. The interface between intellectual property rights and biological diversity was being discussed in a number of international fora. In addition to the discussion in the TRIPS Council, her delegation continued to consider the discussions at the WIPO to be important.

66. The representative of Canada associated his delegation with the points made and the questions raised by the delegations of New Zealand and Australia. He saw no conflict between the TRIPS Agreement and the CBD and said that each should be implemented in a mutually supportive manner. He said he was not convinced that patent law was the best means to ensure prior informed consent and access and benefit-sharing, or that an amendment to the TRIPS Agreement was the best way forward. However, he recognized the mandate in paragraphs 12 and 19 of the Doha Declaration and the July 2004 Framework.

67. He appreciated the exchange of views between the delegations of Peru and the United States, which had been based on real life situations and recalled that Canada had encouraged the proponents to elaborate on how their approach would have addressed real life situations. Such a diagnostic approach would help the Council and Members, who had not yet come to a firm view on these issues, to find the best way forward to prevent biopiracy. Recognizing that the submission of the EC had been to WIPO, he said that that forum continued to provide the best opportunity to resolve the questions on the relationship between intellectual property, genetic resources, traditional knowledge and folklore.

68. The representative of Kenya associated his delegation with the papers that had been circulated by Brazil and other delegations. In his view there was a need to review and amend the TRIPS Agreement to prevent biopiracy, to ensure that every patent applicant disclosed the country of origin of any traditional knowledge involved in the invention, obtained prior informed consent and based access to genetic resources on a fair and equitable sharing of benefits. He supported the position of the European Communities regarding the need for a mandatory requirement for disclosure. His delegation was of the view that a combination of national and multilateral approaches would be the most appropriate means to tackle the problem.

69. The representative of Japan said that there was no conflict between the TRIPS Agreement and the CBD and that they should coexist in a mutually supportive manner. He said that the discussion on what should be disclosed in a patent application should be based on the requirements of the patent system *per se*. The disclosure issue should be discussed mainly at the IGC of the WIPO because of its

expertise and because its Director-General had shown his strong support to that forum. His delegation shared many views with the United States, as stated in their paper as it proposed to make some impact on biopiracy without putting additional burden on to the patent system.

70. The representative of Peru said that his country faced similar problems as described by Brazil with respect to genetic resources from the Amazon region, with regard to some products on which the National Anti-Biopiracy Commission was currently carrying out research. He said that document IP/C/W/442 closed the circle that had started with the presentation of the checklist and the development of each of the issues. He believed that IP/C/W/443 contained the majority of the concerns that Peru and other developing countries had with regard to the contract-based approach. He was concerned that the contractual approach was still being considered as a possible solution to the problems faced by developing countries. He thanked all those who had made comments on the Peruvian paper, especially the delegations of Canada, New Zealand and Australia, who had promoted the presentation of real life cases.

71. Responding to some of the comments made by the delegation of the United States, he said that it had not been said that the presentation of a patent application constituted proof of misappropriation or biopiracy. He clarified that the six examples that had been included in the paper were illustrative. The National Anti-Biopiracy Commission had identified approximately fifty products but this did not mean that misappropriation or biopiracy had in fact taken place in all these patent applications. This was the first part of the work to be carried out by the Commission where all the possible applications containing Peruvian genetic resources would be identified. In a second phase, they would identify the applications where the Peruvian National Authorities considered that there could have been misappropriation in order to present the case to revoke such patent applications. The United States delegation had mentioned the case of *Maca* and Peru had avoided presenting it, since some patents granted were already in the phase of revocation. A similar process might be carried out with a product known as *Chancapiedra*, which had cosmetic uses.

72. He said that the delegations of the United States and Japan had stated that the disclosure issue should be discussed at the WIPO. The WIPO had addressed this issue in the Committees dealing with patents and in the IGC. The IGC's mandate concluded this year with the last meeting to be held in July 2005 and there was no clarity on the continuation of its work. The IGC had no negotiating mandate and could not address the problems faced by the TRIPS Council on the need to include a universal, legally binding requirement to disclose origin. While the patent committees dealt with this issue, they had a limited scope. For example, Peru was not a party to any of the patent treaties of the WIPO. Therefore, the TRIPS Council was the appropriate forum to deal with the disclosure issue. He hoped that the decision to carry out dedicated informal consultations would allow the work with to be continued the objective of reaching a consensus, either in July or by the Ministerial Conference in Hong Kong, China on a work plan which would allow a satisfactory solution by the end of the round.

73. He said that even though Peru had an obligation to disclose origin in its national legislation, it was very difficult to implement since the Peruvian patent system granted only five or ten patents per year and could not be compared to those of the United States, Europe or Japan. Consequently, a country like Peru had to search, not in its own patent system, where there was an obligation to disclose origin, but in those countries where the majority of patent applications were presented and where the large corporations could carry out research and development using foreign genetic resources. He repeated that this did not mean that all the genetic resources originating in Peru were misappropriated, or that all the patent applications involved biopiracy. He explained that if the obligation to disclose origin in the patent application was properly implemented with an universal, legally binding requirement, it would be much easier for countries like Peru to search for specific cases, without having to go through expensive legal procedures, unlike the current situation with respect to patents involving the use of *Maca* where, were it not for international support and NGOs, the Peruvian government would have found it impossible to present the cases on revocation of patents

in foreign countries. He concluded by saying that the development round had to take into account the fact that developing countries were burdened with all these costs. While the obligation to disclose origin would probably imply a cost, it was smaller than the costs that countries like Peru had had to face in creating the National Anti-Biopiracy Commission, carrying out searches, etc. He said that the questions posed had allowed him to further clarify how the National Anti-Biopiracy worked, the problems it faced and the difficulties that might be avoided with the inclusion of a mandatory requirement of the disclosure of origin through an amendment of the TRIPS Agreement.

74. The representative of Switzerland recalled several oral interventions of his delegation, and the three communications to the TRIPS Council contained in documents IP/C/W/400, IP/C/W/423 and IP/C/W/433 on the proposal that had been submitted to the Working Group on the reform of the Patent Cooperation Treaty of the WIPO. These proposals would enable the contracting parties of the PCT to require patent applicants to disclose the source of genetic resources and traditional knowledge in patent applications.

75. He supported the proposal of Canada that the discussion under paragraph 19 should be aimed at a more fact-based approach and that the discussions could benefit from national experiences with respect to access and benefit-sharing systems. The Council had gained a better understanding of the challenges and shortcomings that might occur in practice from the paper and the explanations submitted by the Peruvian delegation. His delegation was of the view that the process should be Member-driven and encouraged other Members to come up with such information.

76. With regard to the communications IP/C/W/429/Rev.1 and IP/C/W/438, which had been submitted by Brazil, India and various other delegations, his delegation had four questions. First, how did these delegations define the term "country of origin"? Second, what was the reason that these communications only referred to the country of origin? He highlighted that Article 15 of the CBD in the context of access and benefit-sharing did not refer to the country of origin, but referred to the contracting party providing genetic resources. In the view of his delegation the wording "country of origin" excluded the International Treaty of FAO, since it was not based on a bilateral, country-by-country approach but established a multilateral system of access and benefit-sharing. The same problem applied to the proposals that had been submitted by the EC and the US. The third question was how did these delegations define the terms "biopiracy" and "misappropriation"? He said that having a clear understanding of these terms and the underlying concepts was a crucial prerequisite for the discussions in the TRIPS Council. The fourth question was how would the proposals of these delegations be reflected in WIPO's PCT and PLT?

77. Responding to the United States' submission (IP/C/W/434), he said that with respect to prior informed consent and benefit-sharing, his delegation had stated in its communication of June 2003 (IP/C/W/400/Rev.1), that the task of verifying whether the national system of prior informed consent had been adhered to and if the benefits had been shared could best be carried out by the parties to the contracts on access and benefit-sharing. He proposed to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and genetic knowledge and to establish a list of government agencies which could be informed by the office receiving a patent application containing such a declaration. These two measures would allow the parties to the contract on access and benefit-sharing to verify whether the other contracting party had complied with its obligations arising under that contract and would simplify the enforcement of these contractual obligations.

78. He asked how a purely national approach would address problems arising from transboundary access and benefit-sharing in cases where genetic resources and traditional knowledge were being used outside the scope of national solutions. Further it was not clear how a purely contractual approach would address cases where no contract on access and benefit-sharing had been concluded between the provider and the user of genetic resources and traditional knowledge. He was also interested in receiving further information from the European Communities and its member States on the specific PCT and PLT provisions which would need to be changed in implementing their proposal.

79. The representative of the Philippines said that his country had also faced situations which could be characterized as unfair or inequitable exploitation of biological and genetic resources or traditional knowledge. He supported the objective of the proponents in seeking a solution through the disclosure requirement, which could indeed provide the basis for a multilateral solution to the problems associated with biopiracy. The requirement of providing evidence of benefit-sharing was most commercially and economically meaningful in the context of the WTO and the TRIPS Agreement. If the premise of the supposed link between intellectual property rights and trade was accepted, presumably through the importation and utilization by the prospective patent applicant of biological resources and traditional knowledge into his home country and their international marketing, then disciplines requiring evidence of benefit-sharing would potentially offer the most trade-related of the three requirements that the proponents had suggested. National schemes, such as contractual arrangements, had not proven to be adequate in ensuring benefit-sharing. A requirement for patent applicants to disclose evidence of benefit-sharing and prior informed consent could be seen as an alternative to national access and benefit-sharing schemes. However, national benefit-sharing schemes in themselves should be strengthened, in particular to ensure that the internal allocation of benefit-sharing reaches those peoples or parties that were actually the source of the genetic or biological resource or traditional knowledge.

80. He said that the suggested international framework contained in document IP/C/W/442 might be pursued in parallel in various forums to truly attain an effective international protection. He encouraged the proponents to look more closely at the aspect relating to the legal effects of not providing evidence of fair and equitable benefit-sharing under the relevant national regime. The issue of how to enhance the existing mechanisms for benefit-sharing in relation to commercialization outside the patent system should be pursued in order to obtain a fully effective international framework of protection, although this was outside the jurisdiction of the TRIPS Council. It was also critical to look at how adequate compensation could be ensured, particularly where the patent had already been granted.

81. The representative of Malaysia said that there was a number of Members interested in a system of protection of genetic resources and traditional knowledge that was effective and benefited both the patent applicants and the owners of such resources or knowledge. She looked for further clarification of how this system would work in a practical and operational manner. She said that IP/C/W/442 stated that there should be evidence of fair and equitable benefit-sharing based on national law. This requirement would not be cumbersome, as the applicants had simply to supply information of full compliance with the laws of the country of origin. However, it was not clear who determined whether the requirements had been met by the applicant, whether it should be the patent office or the national authority of the country of origin. If it was the patent authority or even the courts of the country where the patent office was located, how would such authorities be able to judge adherence to laws outside their own jurisdiction? It was not clear if the patent authorities would be able to conduct this task with due diligence and commitment. Certification systems of compliance at the national or international levels had been mentioned, but it was not clear what would happen in cases where the beneficiaries had not been clearly identified or where the source or origin was unknown. She sought clarification on whether a patent application could still continue even if benefit-sharing could not take place due to these reasons.

82. The representative from Brazil recalled that his delegation, together with the Indian delegation, had tabled a document containing a commentary on the issues raised by the United States in document IP/C/W/434. He said that they were willing and open to consider any additional issues that the United States would like to raise on the responses contained in their submission. He said that his delegation was ready to engage on the issue of the role of patent offices and definitions. These were important technical matters that had to be addressed in the course of negotiations

83. He responded to the argument that had been made on the suggestion that disclosure of origin was not feasible and should not be included in the TRIPS Agreement because it would not solve all of the problems that developing countries were facing. He emphasized that the disclosure requirement was not intended as a stand alone mechanism but could make an important contribution in addressing the concerns that had been raised by developing countries. The international patent system and the TRIPS Agreement would be improved by such an obligation as it would provide for a more cost-effective system to pursue appropriate actions in response to cases of biopiracy and misappropriation.

84. In response to the point that there was no reference in the CBD to disclosure of origin, he pointed out that an article of the CBD did state that the parties to that convention should take measures to ensure that intellectual property rights were supportive of and did not run counter to its objectives. The TRIPS Agreement was an international intellectual property agreement administered by the WTO and that was the reason why the group of developing countries had come to this forum to present their proposals and it had a role to play to ensure that the objectives of the CBD were not undermined.

85. With respect to the issue of the absence of national regimes, he said that the submissions did state that, for cases where national access and benefit-sharing regimes were not available in the country of origin, patent applicants would merely have to make such a declaration. He pointed out that the CBD was an international agreement and that prior informed consent and benefit-sharing, as embodied in the CBD, were to be respected even in cases where specific ABS regimes might not have been set up in the countries of origin. Responding to the point made with respect to the burden on patent offices and patent applicants, he said that this argument was not relevant since the TRIPS Agreement had created a significant burden, particularly on developing countries and impoverished peoples and consumers of technology in general.

86. With respect to arguments on appropriate forum, he reiterated that there was a mandate from the Ministers to address this issue and encouraged all delegations to engage constructively in the discussion and refrain from engaging in "forum shopping". He said that the TRIPS Council had also been charged with taking into account the development dimension in its future work. It was up to WIPO Member States to ensure that their interests were properly taken care of in the work of that organization, not only in the context of the PCT and the PLT, but also the SPLT. He pointed out that the discussion in the TRIPS Council had, in fact, moved work forward on the disclosure issue and the relationship of the TRIPS Agreement and the CBD. These discussions had allowed the proponents to present the technical points that would have to be considered in the course of the negotiations for an amendment of the TRIPS Agreement.

87. The representative of India said that he disagreed with the statement of the US delegation that there was a growing recognition that the disclosure requirement was not an adequate solution. The discussions that had taken place had shown a growing realization that disclosure requirements were an integral component of the eventual recommendation that the TRIPS Council had to make under paragraph 19 of the Doha Ministerial Declaration. The US delegation also said that it appeared there was a growing recognition in favour of the national contract-based approach whereas, in his view, there was a diminishing recognition of the stand-alone contract based approach being an adequate solution to the issue of the relationship between the TRIPS Agreement and the CBD.

88. He agreed that patents *per se* did not constitute misappropriation, but said that the act of applying for a patent and the acts involving the accrual of rights on patents without proper authorization did in fact constitute misappropriation, as stated in the submission IP/C/W/443. The United States had also stated that there were a wide variety of restrictions on the use of patented products and an example characterized as environmental restrictions had been given but did not pertain to the obligations arising out of the CBD.

89. With respect to criminal or civil liabilities, he said that it was not clear what would happen when the misappropriation involved transboundary activities and was happening outside the jurisdiction of the national enforcement authorities. He concluded that it was clear from the discussion that national systems were important, but not sufficient to resolve the issue that was being discussed.

90. He agreed that prior informed consent and access and benefit-sharing issues had to be responded to as a first step through a national level system of requirements, but he believed that an international recognition of the need for respecting these prior informed consent and access and benefit-sharing requirements was essential to achieve the shared objective of mutual supportiveness of the CBD and the TRIPS Agreement. The mutual supportiveness of the CBD and the TRIPS Agreement would be achieved in part through the national regimes and other international treaties in other bodies, but the linkage with the TRIPS Agreement for the achievement of these objectives had to be addressed in the WTO.

91. In response to the point made by the Australian delegation that the disclosure requirement might undercut the objectives of the patent system, he believed that the TRIPS Agreement provided for a balance between rights and obligations that the society at large would benefit from. With respect to the point on costs and burdens referred to paragraph 5 of document IP/C/W/429/Rev.1, he said that these arose for those who had to use post-grant proceedings to achieve what could have been achieved if there had been adequate knowledge through disclosure of the origin of the biological material and associated traditional knowledge that was used in an invention.

92. In response to the point made by the European Communities on the role of patent offices in the disclosure requirement, he said that their role was to ensure that patent applications were complete and these did not add any burdens. He said that a combination of national level regimes and the international recognition of the disclosure requirements was the minimum required to meet the shared objectives. He said that the definitions sought to be established by the Swiss delegation would be useful when the technical phase of undertaking the amendment of the TRIPS Agreement took place.

93. He referred the delegation of the Philippines to the three papers submitted by his delegation and the cosponsors on the potential legal effects of the disclosure requirements and was ready to discuss any further concerns. He said that he would revert to the technical comments from some delegations. He proposed that in the forthcoming meetings of the TRIPS Council there should be a more technical discussion on the specifics of the amendment to the TRIPS Agreement.

94. He said that the Doha Ministerial Declaration had placed the needs and interests of developing countries at the heart of the work programme it had adopted. Ministers had also strongly reaffirmed their commitment to the objective of sustainable development. They were convinced that the aims of upholding and safeguarding an open and non-discriminatory multilateral trading system and protecting the environment and promoting sustainable development could and must be mutually supportive. This applied to all the agreements administered by the WTO, including the TRIPS Agreement.

95. The mandate of the negotiations in the Doha work programme tellingly started with implementation-related issues and concerns. Paragraph 12 of the Doha Declaration highlighted the "utmost importance" attached to these concerns, a term not used anywhere else in the entire Declaration. It then expressed determination to find appropriate solutions to these issues. Negotiations on outstanding implementation issues were an integral part of the work programme. One needed to keep the outcome mandated in the Declaration and the process of organizing these negotiations in view when proceeding to find appropriate solutions.

96. There were half a dozen TRIPS outstanding implementation issues, most of which related to the relationship between the CBD and the TRIPS Agreement. An outcome on this issue, therefore, was of utmost importance. A number of delegations, including India, had suggested that one part of the solution was to require patent applicants to disclose the country and source or origin of any biological material and/or associated traditional knowledge used in the invention as well as evidence of prior informed consent and benefit-sharing that may have been obtained in accessing the material and/or knowledge. He believed that the consultations should lead to a satisfactory outcome on this "disclosure issue". He was sure that all Members wished an outcome on this issue and thereby to fulfil the mandate given by Ministers. It was clear to India that a satisfactory outcome on this issue was essential for the conclusion of the Doha work programme.

97. The 1 August 2004 Decision by the General Council Decision, in particular the paragraph on "Implementation", had reminded Members that they had not yet progressed enough on issues that were at the heart of the work programme, including implementation issues. The Director-General had been requested by the General Council to continue his consultative process and to report to the TNC and the General Council no later than May 2005 in order to enable the General Council to take appropriate action by July 2005. Efforts needed to be redoubled to find appropriate solutions as a priority. He called upon the Chairman, in his capacity as a Friend of the DG, to structure a substantive, dedicated and inclusive consultation on the disclosure issue. The consultations should lead to a satisfactory outcome on this proposal.

98. The Council took note of the statements made.

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

99. No statements were made under this agenda item. The Council agreed to revert to the matter at it's next meeting.

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

100. No statements were made under this agenda item. The Council agreed to revert to the matter at it's next meeting.

H. DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

101. The Chairman recalled that, at its meeting in June 2004, the Council had agreed to continue its work pursuant to paragraph 11 of the General Council Decision on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (hereinafter referred to as "the Decision") on the preparation of an amendment to the TRIPS Agreement with a view to the TRIPS Council making a recommendation by the end of March 2005 so that the General Council could conclude its work on the amendment at its first meeting thereafter.

102. He informed the Council that, as had been agreed at its meeting in December 2004, he had continued to consult with delegations individually and in groups, as well as in open-ended format on the best way to proceed on this matter. However, there seemed to remain significant differences among delegations in regard to the substantive content of an amendment to replace the Decision, although there had been some signs of flexibility on the issue of the legal form.

103. He drew attention to three new communications; one from the delegation of Rwanda on behalf of the African Group providing arguments to support the African Group proposal on the implementation of paragraph 11 of the Decision (IP/C/W/440, referring to an earlier proposal by the African Group circulated as document IP/C/W/437); another from the delegation of Barbados on behalf of the Group of Commonwealth Developing Countries containing a "Report on the Workshop on the WTO Decision on Access to Medicines at Affordable Prices for Countries with No or Insufficient Manufacturing Capacities", that was organized by the Commonwealth Secretariat in Geneva from 12 to 14 October 2004 (IP/C/W/439); and a third from the United States commenting on the implementation of the Decision (subsequently circulated as document IP/C/W/444).

104. Introducing document IP/C/W/440, the representative of Nigeria, speaking on behalf of the African Group, recalled that, at the Council's meeting in December, the African Group had presented a proposal for the amendment of Article 31 of the TRIPS Agreement. The proposed amendment was based on the waivers adopted in the Decision with modifications, but it did not include the Chairman's Statement either as part of the amendment text or as a footnote. Some Members' concerns about and arguments against the proposed approach gave rise a number of issues. In this respect, he noted that some Members had argued that there was no need to amend the text of the TRIPS Agreement and maintained that a footnote would be the most appropriate way to implement paragraph 11 of the Decision.

105. He recalled that, in its note of 1 March 2004, the Legal Affairs Division had concluded that footnotes were considered by WTO panels and the WTO's Appellate Body as being integral parts of the articles to which they were attached. In an addendum to this note, dated 12 May 2004, the Division had further concluded, that the legal effect of a reference to another document, whether in the main body of the Agreement or in a footnote, would obviously depend on the way the reference was written. The same addendum also stated that there was no reason emanating from the law and jurisprudence of the WTO to date that would prevent Members from using other options, including making additions to an article of the Agreement, modifying the relevant paragraphs of Article 31 of TRIPS, or inserting an annex.

106. Therefore, he considered that the proposal by the African Group to add a new paragraph to Article 31 would stand on sound legal ground in the WTO law and jurisprudence as confirmed by the Secretariat. This would be the most direct and straightforward approach, which left no doubts about the legal standing of the amendment. As was clear from the Secretariat's notes, while panels and the Appellate Body had generally interpreted footnotes as a substantive part of the text, the question of the status of footnotes vis-à-vis the text of an amendment had never been positively examined by a panel or the Appellate Body. It would therefore be uncertain if a footnote could have the same substantive value as an embodiment into the text of the Agreement.

107. Turning to the modifications to the Decision proposed by the African Group, he explained that those were based on the agreement that the "amendment would be based on the Decision, where appropriate". The African Group proposal would modify the Decision as appropriate and, in particular, eliminate a number of provisions in the Decision, while maintaining the fundamental elements and substance of the Decision. First, those provisions whose purpose had already been served or which would be redundant in the context of an amendment could be seen as self-eliminating elements. This would include the Preamble, the last part of paragraph 1(b), dealing with Members that voluntarily decided not to use the system or to use it only in limited circumstances, as well as

paragraph 6(ii) on regional patent systems, paragraph 8 on annual reviews, paragraph 9 on prejudice to other rights, and paragraph 11 on the amendment process.

108. Second, provisions whose purpose was served by other provisions of the TRIPS Agreement, such as those on enforcement and the already existing provisions of Article 31, were also proposed for elimination. This category would comprise most of the provisions of paragraph 2 of the Decision, namely paragraph 2(a)(i) requiring the specification of the names and quantities needed, paragraph 2(a)(ii) relating to the confirmation of lack of capacity and the Annex to the Decision, paragraph 2(a)(iii) relating to the confirmation of intention to grant a compulsory licence, paragraph 2(b)(i) regarding the importation only of the amount necessary to meet the needs of the importing Member, paragraph 2(b)(iii) on the posting of information on the website, as well as paragraph 2(c) with respect to the notification to the TRIPS Council of the grant of a licence.

109. It was also proposed to eliminate paragraph 4 of the Decision relating to re-exportation, since the patent holder would have sufficient avenues to prevent re-exportation of the products manufactured under the system. Therefore, paragraph 4 would only complicate the implementation of the system without adding any value to it. The most important component of preventing diversion would be in third countries. This aspect would be adequately covered by Article 31(2)(d) of the African Group proposal, which incorporated elements of paragraph 5 of the Decision, with modifications to include the fundamental elements of paragraph 4.

110. As to the Chairman's Statement, he said that it should not be part of the amendment as it was not part of the Decision. Making it part of the amendment text, including through a footnote, would elevate its legal status.

111. Introducing document IP/C/W/439, the representative of Nigeria made a statement on behalf of the Chairman of the Geneva Group of Commonwealth Developing Countries on the main findings and conclusions of the Workshop on the WTO Decision on Access to Medicines, held in Geneva from 12 to 14 October 2004 and organized by the Commonwealth Secretariat in cooperation with the Geneva ACP Office and the Agency for International Trade Information and Cooperation (AITIC).

112. As regards quality, safety and effectiveness of products produced under compulsory licences, the meeting had noted that a number of countries which were important producers of pharmaceutical products would not require manufacturers to obtain market authorizations for products that were produced only for exports. The responsibility for the evaluation of generic medicines would therefore fall on the drug regulatory authorities of the importing countries. However, a lack of qualified and trained human resources, as well as well-functioning laboratory facilities, would often make it difficult for regulatory authorities, particularly in countries with insufficient or no manufacturing capacities, to carry out independent evaluations that were needed for the granting of marketing approvals of such products. Moreover, according to the WHO, nearly one third of such countries would have either no regulatory authority or only limited capacity to regulate the market for pharmaceutical products.

113. In view of this situation, the meeting had considered the need for a country granting a compulsory licence to produce only for exports to ensure that exports were permitted only after quality and safety evaluation of the product by its regulatory authority. It was noted that some countries had recently initiated relevant legislation. Where this could not be achieved through legislation, the exporting country should invariably impose conditions in the compulsory licence that exports could be made only after the product had been evaluated by the drug regulatory authority, or, alternatively, allow the importing country to request the drug regulatory authority of the exporting country to make the necessary evaluations. The meeting had also noted that it might be possible for importing and exporting countries to agree on replying on the WHO scheme for pre-qualification of

manufacturers and products, for the assurance of quality of products produced only for exports in accordance with the provisions of the WTO Decision.

114. He reported that the workshop had also discussed the feasibility and desirability of developing trade and production on a regional basis. It was noted that the flexibility to resort, where necessary, to compulsory licensing would only be available to developing countries which were members of regional economic groupings of which half the members were least-developed countries. The development of a pharmaceutical industry would require a number of critical resources. Incentives would be necessary to encourage the development of such industry, which would require ensuring resource-sharing and industrial complementarity.

115. As regards the desirability of developing regional patents, there had been consensus on the necessity for engaging in further discussions on the practical steps that would have to be taken for the development of trade and production on a regional basis. It had been agreed that the secretariats of the regional economic groupings and the regional patent organizations should be engaged. The Commonwealth Secretariat, the Geneva Office of the ACP Secretariat and AITIC had indicated their willingness to consider providing technical assistance on request for further work in these areas.

116. As regards the implementation issues, it had been noted that one of the positive aspects of the Decision was the fall in prices of a number of patented products supplied to developing countries. Some evidence showed that there was greater willingness on the part of some patent holders to grant voluntary licences to firms wishing to produce generic drugs.

117. The possible implications of the approach adopted in the free trade area agreements between some developed and developing countries had also been discussed, especially with regard to rules relating to the protection of undisclosed test data submitted by the innovator applicant to the drug regulatory authority for obtaining marketing approval of its product. Some concerns continued to prevail that these developments made it difficult for generic manufacturers to obtain approvals for their products during the period when such data was protected.

118. He reported that the workshop had also noted that least-developed countries benefited from a transitional period until 1 January 2016 to change their national legislations in the pharmaceutical sector and bring them into conformity with their TRIPS obligations. There had been a brief discussion on whether these countries would be able to effectively take advantage of the extended transitional period to develop production of generic versions.

119. In concluding, he highlighted one of the important findings of the Workshop, i.e. the need to pay greater attention to the regulatory aspects of production and trade in pharmaceutical products in further discussions on securing effective implementation of the Decision and work on making available pharmaceutical products that were needed in developing countries at affordable prices. The countries with no or insufficient manufacturing capacities would no doubt be in need of pharmaceutical products for the treatment of diseases like HIV/AIDS, malaria and tuberculosis at affordable prices. However, it would have to be ensured that products supplied to them met the required quality and efficacy standards in the treatment of the ailments affecting people in these countries.

120. Addressing many of these and other issues raised in the discussions required a greater degree of cooperation and coherence at the national level between ministries of trade, industry and health, and between relevant international organizations dealing with health, trade and industrial development. The Workshop had recommended that in further work this aspect should be given due importance.

121. Introducing document IP/C/W/444, the representative of the United States noted that the purpose of the solution reached in August 2003 would have to be kept in mind when transforming it into an amendment to the TRIPS Agreement. The Decision represented a comprehensive and balanced system which allowed those that lacked the capacity to manufacture drugs to import the drugs they needed without drugs being diverted to other markets. It met the objectives that Members were seeking and had garnered support from all WTO Members. His delegation strongly supported the Decision and also encouraged and supported Members' effective and appropriate use of the solution. His delegation also remained committed to expeditiously reaching consensus on an amendment to the TRIPS Agreement that fully reflected the solution. He said that the amendment would have to preserve the entire agreement reached by consensus in August 2003, and, therefore, would have to include an express reference to both the Decision and the Chairman's Statement. As was the case for many other delegations, he believed that this should be a technical exercise and that substantive issues should not be re-opened. However, the task of reaching an agreement for an amendment preserving all aspects of the Decision would be very difficult if Members sought to change its content.

122. As regards the African Group proposal, he expressed serious concerns about the suggested amendment to the TRIPS Agreement to implement the Decision. For example, the proposal did not make any reference to the Chairman's Statement, and omitted key safeguards from the Decision to ensure the proper functioning of the solution, such as notification and diversion. His delegation believed that any proposal would have to meet the basic objective of formulating an amendment that preserved the consensus and delicate balance struck by Members in August 2003. It remained open as to how this technical exercise could be best and most expeditiously accomplished. A footnote approach referring to both the Decision and the Chairman's Statement would be an easy and straightforward exercise and, therefore, an optimum solution. But any other options for an amendment including both the Decision and the Chairman's Statement could be considered, including a new section in Article 31 of the TRIPS Agreement itself.

123. He recognized that some Members had expressed concerns about the legal status of the Chairman's Statement being elevated. He clarified that his delegation did not seek to elevate the legal status of the Statement. However, all aspects of the Decision should be preserved, including the legal relationship between the Decision and the Chairman's Statement. His delegation was open to discuss how best to describe the relationship between the content of the Statement and the Decision. However, it was essential to preserve explicitly in the amendment a reference to the Statement or the principles included therein. The Statement had made the consensus solution possible by addressing and resolving questions concerning aspects of the Decision that were unclear or not addressed. Therefore, the Statement was an essential part of the consensus solution which had to be preserved. Eliminating the principles of the Statement would make it very difficult if not impossible to move forward.

124. The representative of the European Communities confirmed that the EC remained fully committed to the amendment process and to the March 2005 deadline to complete work on the amendment. His delegation, therefore, continued to believe that this process should remain a purely technical exercise without any re-opening of the discussion on substance. The Decision was not perfect but reflected a compromise that had been difficult to reach. Therefore, any attempt to renegotiate it would jeopardize the amendment process. His delegation had the impression that certain Members were trying to obtain what they were unable to achieve in August 2003. It was, therefore, doubtful if those Members really wanted to complete work on the amendment expeditiously and even wanted an amendment at all. To further the process and preserve its technical nature, he suggested that the Chairman, with the possible assistance of the Secretariat, continue consultations and produce a text consisting of a technical adaptation of the Decision.

125. As regards the African Group proposal, he said that it adopted a "pick-and-choose" approach. Several provisions of the Decision had been eliminated, and others redrafted. His delegation did not share this approach and considered that the WTO Decision was the result of a delicate balance that was difficult to strike. The integrity of the Decision should, therefore, be preserved. He then summarized the most problematic points of the African proposal.

126. As regards product coverage in paragraph 1(a) of the Decision, the words "among others" had been added in the definition. This would broaden the scope in an unacceptable manner. The terms "products (…) of the pharmaceutical sector" used in the Decision would, for example, be broad enough to encompass vaccines, even though they were not expressly included in the definition. With respect to notification and transparency requirements in paragraph 2 of the Decision, most provisions had been removed, including the requirement that the importing country must notify the name and expected quantities of the product needed, the confirmation that the importing country had established a lack of domestic manufacturing capacity and detailed notification requirements applying to manufacturing companies and exporting countries. Those provisions were important and should be restored.

127. Paragraph 3 of the Decision on remuneration had been substantially changed, proposing that the remuneration should be paid in the importing Member instead of the exporting Member as stipulated by the Decision. Anti-trade diversion measures by importing and exporting Members in paragraphs 4 and 5 of the Decision had been merged in the African Group proposal, resulting in a weakening of the obligation on importing Members. Maintaining the carefully drafted anti-trade diversion measures was a fundamental element to ensure that the system worked effectively and importing countries took their part of the responsibility, within reason, to prevent trade diversion.

128. He noted that two important elements had been removed in the African Group proposal as regards regional cooperation addressed in paragraph 6 of the Decision, namely the reference to the principle of territoriality of patent rights and to the establishment of regional patents. It was not acceptable for his delegation to eliminate a fundamental aspect of international patent law, such as the principle of territoriality. As regards transfer of technology in paragraph 7 of the Decision, the proposed draft would completely change the original purpose. Instead of overcoming the problem identified in paragraph 6 of the Doha Declaration, the objective would now be to help importing Members establish their own manufacturing capacities in the pharmaceutical sector. Finally, the requirement in paragraph 8 of the Decision to conduct an annual review of the functioning of the system had been completely removed. These few examples showed that the African proposal contained substantive changes which were not acceptable for his delegation since they would re-open the whole discussion on the Decision.

129. As regards the communication from Rwanda on behalf of the African Group on legal arguments to support the African Group proposal, he noted that his delegation could agree with several aspects raised therein. For example, the footnote approach was not the most appropriate way to implement paragraph 11 of the Decision. A footnote was acceptable only if its wording clearly set out a legal exception to Article 31(f). An amendment of the TRIPS Agreement inserting textual changes in the body of the Agreement was preferable. His delegation also agreed that the legal status of the Chairman's Statement should not be upgraded. However, the link between the Decision and the Statement should be preserved. The suggestion by the African Group to read some form of the Chairman's Statement at the time of the adoption of the amendment could be considered, alongside other options. His delegation was, however, not convinced by the justifications put forward by the African Group for the modifications to the Decision. The amendment process should remain a purely technical exercise without any re-opening of the discussion on substance. The interpretation made by the African Group of the terms "based on the Decision, where appropriate" contained in paragraph 11 of the Decision was much too broad. These terms could not be understood as meaning re-discussing every provision of the Decision.

130. As regards the report on the Geneva Workshop on the WTO Decision on Access to Medicines in October 2004, submitted by the delegation of Barbados on behalf of the Group of Commonwealth Developing Countries, he said that the outcome was very useful, in particular for countries in the process of implementing the Decision. An important issue had emerged from the discussion, i.e. the necessity to ensure that products supplied to countries in need would meet the required quality and efficacy standards. In most cases, the countries of destination would not have the required regulatory or scientific capacities to carry out the necessary testing of the pharmaceutical products manufactured under a compulsory licence. Therefore, the licensee could be asked by importing countries to prove the safety and efficacy of the products. He confirmed that this concern had been taken into account in the draft EC legislation implementing the Decision. To ensure that patients from countries in need benefited from the same level of safety, quality and efficacy as European patients, the competent authorities in the EC would be entitled to deliver a scientific opinion for medicinal products for supply outside the European market.

131. The representative of Kenya, referring to the issue of remuneration in paragraph 2(b) of the African Group proposal raised by the European Communities, said that the present drafting should be corrected so as to clarify that, where use was made of the system by an eligible importing Member, adequate remuneration should be paid by the exporting Member, and not the importing Member.

132. The representative of Korea said that his delegation remained committed to reaching an agreement on the amendment by the March 2005 deadline. The Decision was the result of difficult and long negotiations and reflected a delicate balance of interests among all Members. Therefore, from the very start of the discussion on an amendment, his delegation had supported the view that the amendment should remain a technical exercise and that the substance of the Decision should not be re-opened. The African Group proposal modified the Decision by eliminating some provisions and re-drafting the wording of a few other provisions. While it would be sensible to eliminate those provisions whose purpose had already been served, such as the Preamble and paragraph 11 of the Decision, he, however, was not convinced that the elimination or modification of other provisions would be necessary or justified. For example, the African Group proposal introduced significant changes to paragraph 2, including the attached Annex, and paragraph 4, which set out important requirements for importing and exporting Members to ensure that the system worked as intended and prevented illegitimate product diversion. He did not believe that the existing provisions of the TRIPS Agreement provided a safeguard mechanism of similar effect as claimed by the African Group.

133. He noted that the African Group proposal was based on an appropriateness test looking at whether a particular provision was necessary for the proper functioning of the amendment. This approach posed a number of difficulties in application. In view of the difficulties Members had had in the course of reaching agreement on the Decision, and the problems raised by the African Group proposal, a more pragmatic approach could be to look at whether keeping certain provisions of the Decision would hamper the proper operation of the amendment. His delegation believed that the majority of the provisions in the Decision would not do so. The African Group proposal itself had not stated that the provisions proposed for modification or elimination would negatively affect the operation of the amendment. It had merely claimed that those provisions were either redundant or covered by existing provisions of the TRIPS Agreement. Maintaining redundant provisions would be preferable to changing the substance of the Decision and the risk of not reaching an agreement within the timeframe.

134. As regards the form of the amendment, his delegation could be flexible provided that the entirety of the substance of the Decision was preserved. The most straightforward and direct solution was to put the amendment text in the main body of the Agreement.

135. He agreed that the Chairman's Statement was an integral part of the solution that had led to the adoption of the Decision. As explicitly stated therein, it represented several key shared understandings of Members regarding the Decision, its implementation and interpretation. When amending the TRIPS Agreement, it would be necessary to ensure that the content of the Chairman's Statement remained valid. He agreed with the African Group that the legal status of the Statement should not be changed, in particular as regards the voluntary opt-out commitments made by some Members, including Korea, on 30 August 2003. The voluntary nature of those commitments would have to be preserved. He, therefore, welcomed the suggestion of the African Group which considered having some form of a Chairman's Statement read at the time of the adoption of the amendment. This would offer a good solution preserving the content of the Chairman's Statement without changing its legal status.

136. The representative of Canada agreed with those previous speakers that had said that the amendment process should be a technical exercise reflecting the agreement WTO Members had reached in August 2003 and confirmed that his delegation did not see the benefit of re-opening and re-negotiating substantive issues. While recognizing the African Group's view that some provisions of the waiver system were not necessary, he noted that those same provisions, including the Chairman's Statement, had been of great importance to other WTO Members. Their inclusion in the system had been a key element in the consensus and conclusion of those difficult and complex negotiations.

137. Turning to the report on the Workshop on the WTO Decision on Access to Medicines presented by Nigeria, he said he believed that it contained some important information. According to this report, "evidence had confirmed that the prices of certain patented products had fallen compared to the price levels prior to the period when negotiations for adoption of the WTO Decision had commenced. In a few cases, the prices had fallen to nearly one tenth of the prices charged previously. Moreover, the information in the case studies had highlighted a greater willingness of patent holding companies to grant voluntary licences to domestic firms for production of generic versions of patented products". This had been the purpose of the Decision. While recognizing that much more work had to be done and progress to be made, he said that this indicated that the system established under the Decision worked and could be useful to address the public health concerns of developing countries. Taking into account that all delegations agreed on the urgent need for the WTO Membership to act on the problems some developing countries faced in using Article 31 of the TRIPS Agreement, his delegation encouraged all potential exporters and importers to implement and use the waiver system to address the public health needs of developing countries.

138. The representative of Jamaica wished to emphasize one specific aspect resulting from the Workshop on WTO Decision on Access to Medicines, namely the issue of quality, safety and effectiveness in the use of products produced under compulsory licences. Her delegation had been particularly concerned about an assessment carried out by the WHO showing that between 50 to 90 per cent of samples of anti-malarial drugs failed the quality control test and that more than half of the anti-retroviral drugs did not meet international standards. She welcomed steps taken by countries, in particular exporting countries, to amend their legislation to ensure that pharmaceutical products manufactured under compulsory licences for export met the standards of the respective drug regulatory authorities. Countries with insufficient manufacturing capacities in this area relied on expertise of regulatory authorities in developed countries. She also noted the existence of a WHO scheme for pre-qualification for manufactured products, which could be looked into in order to ensure the quality of products for export.

139. Turning to the Decision, she said that her delegation could support some of the views outlined in the African Group proposal regarding the legal form of the amendment. A substantive amendment to the text of the Agreement would be preferable to a footnote for the reasons set out in document IP/C/W/440 introduced by Nigeria. The Chairman's Statement should not be included. It had been

intended as a confidence building mechanism to reach an agreement on the Decision in 2003 and had served its purpose.

140. The representative of Argentina considered the African Group proposal as a substantive and positive contribution which could help to conclude work on the amendment to the TRIPS Agreement within the set timeframe. Nothing in paragraph 11 of the Decision required a transposition without changes. It merely asked for the amendment to be based on the appropriate parts of the Decision. This had been part of the balance struck in 2003. Her delegation concurred with the comments contained in paragraph 10 of document IP/C/W/440 submitted by the African Group. The Decision requested additional and excessive information. In particular, the limitations in paragraph 2(b)(i) could prevent industry from supplying pharmaceutical products under the system. Paragraph 2(b) imposed stricter requirements than for trade of weapons or toxic products and would not be in line with usual commercial practice. Paragraph 2(c) created an additional obligation, modifying the practice in implementing the Agreement. In addition, the establishment of regional patent systems had nothing to do with the Doha Declaration.

141. She said that the Chairman's Statement should not be part of the amendment. It had been a unilateral statement which had not received general endorsement. Turning to the legal form of the amendment, she said that using a footnote was neither the right approach nor provided a safe legal basis for the straightforward interpretation of Article 31 of the TRIPS Agreement. Members needed clarity in carrying out activities which were not permitted at present. In the absence of any precedent regarding such amendments, it was not advisable to rely on the footnote approach.

142. The representative of Japan said that the amendment should remain a technical exercise, implementing what had been agreed into the TRIPS Agreement without interpreting it. As regards the legal form of the amendment, his delegation preferred a footnote referring to the Decision and the Chairman's Statement in order to amend the TRIPS Agreement. Since both texts had been agreed upon, they should not be separated. A footnote would be the simplest and most secure way to reflect the Decision in the TRIPS Agreement and would avoid re-negotiating substantive issues. Other forms of amending the TRIPS Agreement could lead to re-opening the discussion.

143. He said that his delegation had difficulties with the African Group proposal in document IP/C/W/437. First, it had omitted some paragraphs of the Decision, such as paragraphs 2(b)(i) and 4. Second, parts of the Decision had not been adequately reflected or incorporated in the proposal. The proposal did not refer to the Chairman's Statement. The legal arguments submitted in document IP/C/W/440 to support the African Group proposal further highlighted the discrepancy between the proposal and the Decision. This illustrated how difficult the amendment of the TRIPS Agreement would become if the footnote approach were not used.

144. The representative of Uganda, associating himself with documents IP/C/W/440 and 439, said that the Decision was an important step towards ensuring that countries with no or insufficient manufacturing capacities had access to pharmaceutical products at affordable prices required for the treatment of diseases that were prevalent in their territories. Uganda had been looking forward to a stable and predictable mechanism for the strengthening of the Decision and had hoped that this would enable countries faced with emergencies to purchase the needed products from cheaper sources. This would guarantee access to drugs for HIV, malaria and other epidemics at affordable prices, particularly for the poor sections of the world community.

145. He said that Uganda supported the statement made by Nigeria on behalf of the Geneva Group of Commonwealth developing countries in respect of the findings and the conclusions of the Workshop on the WTO Decision on Access to Medicines. The strength of the Decision should not be watered down through regional trade agreements that promote the interests of the pharmaceutical industry at the expense of access to drugs in developing countries. In relation to this, he requested the

US delegation to clarify the statement that had been made at the Workshop by a US delegate that the free trade agreements that the United States had entered into with some developing countries "would not stand in the way of" or affect the utilization of the TRIPS health solution reached on 30 August 2003 to ensure that developing countries that lack manufacturing capacity may import medicines.

146. Uganda welcomed the recommendation made at the Workshop that a regional patent system be developed to promote the development of the production and trade in pharmaceutical products on a regional basis, and proposed that a regional workshop be held to explore the implementation of this recommendation.

147. The representative of Israel welcomed the three new submissions and hoped that agreement on the amendment could be reached by the end of March. While underlining the importance of the amendment, he recalled that a system already existed that enabled those in need to receive the required medicine. However, work had to continue to find a solution that would fit the needs of all Members. Referring to the comments made by a number of Members that the amendment should not change the substance of the Decision, he said that, while Israel accepted that the Decision and the Chairman's Statement formed a package solution, the voluntary nature of Israel's opting out of using the system as an importing Member in certain circumstances was a matter of substance. Therefore, making the entirety of the Chairman's Statement part of the amendment would change the substance of the Decision. While Israel remained flexible on whether the amendment would appear as a footnote or in the text of the agreement, it had to insist that no changes should affect the manner in which Members had voluntarily opted out of using the system.

148. The representative of Turkey said that he was committed to finding a solution within the deadline. He favoured a technical amendment that would transpose the Decision into the body of the TRIPS Agreement, although he could also go along with an outcome which would satisfy the needs of the Decision's target group, namely the African Group, or developing countries and LDCs. Turkey was still unsure about the legal appropriateness of the footnote approach, although it remained flexible. A substantive amendment to an international agreement, such as the TRIPS Agreement, should be made through a textual change in the body of the Agreement. The Decision and the Chairman's Statement reflected a precarious balance which had been reached after long and difficult negotiations. The future amendment should not alter the rights and obligations of Members, particularly the legal status of the Chairman's Statement. It reflected the voluntary nature of the choice by some Members, including Turkey, to opt out of using the system as an importer in certain circumstances, and its status should not be elevated. Therefore, Turkey agreed with the African Group proposal that the Chairman's Statement be re-read in some form at the time of the adoption of the amendment.

149. The representative of Chinese Taipei said that the amendment should remain essentially technical and neutral in nature and clearly translate into the text of the TRIPS Agreement exactly what had been decided, without any risk of alternative interpretations. He noted that, in its new submission, the African Group had explained that paragraphs 2(a)(i) and 2(b)(iii) of the Decision were redundant because the patent owner had to be informed under Article 31(b) of the Agreement. However, he believed that these paragraphs served important transparency purposes and should not be eliminated. Any voluntary undertaking expressed in the Chairman's Statement should remain voluntary in nature and, therefore, he would not support any suggestions that would lead to changing its legal status. In addition, he recalled that the Chairman of the General Council had stated at the meeting of 30 August 2003 that "this statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health".

150. The representative of Hong Kong, China said that the three new submissions were helpful in the search for a solution before the end-March deadline. In order to meet that deadline, the amendment exercise should be a technical one, and Members should avoid renegotiating the

substantive provisions reflecting the delicate balance that had been reached in the Decision. While remaining open-minded as to the form of the amendment, he shared the concern expressed by the African Group and some other Members about the legal certainty of the footnote approach and believed that a substantive textual amendment to the TRIPS Agreement would be a preferable option. His delegation shared the view expressed by the delegations of Korea, Israel, Turkey and Chinese Taipei that the legal status of the Chairman's Statement should not be changed and that the voluntary nature of the partial opt-out by some Members should be preserved and should not be turned into an obligation.

151. The representative of Switzerland said that he was committed to concluding the work on the amendment by the end of March. It was essential that any outcome would reflect the entirety of the substance of the consensus and the solution that had been found by the Membership on 30 August 2003. Only a purely technical amendment could faithfully translate this consensus, which had been achieved only after very long and difficult negotiations and which represented a delicate balance of interests of Members.

152. The communication by the African Group suggested the elimination of a number of provisions of the Decision on the grounds that they were considered redundant. Various substantive parts and provisions had not been included in the draft amendment and others had been shortened, reworded or simply deleted. In consequence, the proposal by the African Group would change the substantive contents of the consensus that had been reached among Members in an unacceptable manner. This pick and choose approach would result in re-opening the negotiations. The Decision that had been the basis of the consensus reached on 30 August 2003 was an integral whole and it was, therefore, not possible to cut out or re-phrase whole paragraphs.

153. A number of Members, including Switzerland, were presently revising their national laws in order to quickly and faithfully implement the paragraph 6 solution as adopted by the WTO General Council. Any re-opening of the consensus found by the General Council would seriously undermine these national revision processes and would endanger – if not prevent – a transparent and uniform use of compulsory licences for the export of pharmaceuticals under the terms and conditions of the paragraph 6 mechanism. Any re-opening of the delicate balance found on 30 August 2003 would have grave consequences for Members needing to address a serious public health problem who could benefit from the currently ongoing national revisions to implement the possibility of compulsory licences for the purpose of exporting needed pharmaceuticals to such countries.

154. What remained to be done by the Council was to find a way to technically transpose the 30 August 2003 solution into the TRIPS Agreement in the most expeditious and efficient manner. For the reasons of legal security, expeditiousness and efficiency, Switzerland had proposed the footnote approach as a practical and straightforward solution. By means of a reference in a footnote to Articles 31 (f) and (h), the five-page text of the Decision could be incorporated as an Annex into the Agreement without upsetting its structure or compromising its readability or comprehensibility.

155. The Chairman's Statement was part of the consensus found on 30 August 2003 and, therefore, an integral part of the paragraph 6 solution. Everybody was aware that there would not have been any solution without the Statement. Thus, it needed to be reflected adequately in the amendment. This could be done in the form of a reference to the minutes of the General Council meeting of 30 August 2003 in the footnote to Article 31(f) and (h) of the Agreement. In that way, the legal status of the Decision and the Chairman's Statement would not be changed. He suggested that the Chairman of the TRIPS Council or his successor should continue informal consultations with the support of the Secretariat in small group constellations so that he could come forward as soon as possible with a draft text on how best to technically integrate the consensus of 30 August 2003 as a whole in the TRIPS Agreement.

156. The representative of the United States, in response to the question from Uganda, confirmed that the provisions in US free trade agreements did not stand in the way of the effective utilization of the TRIPS/health solution reached in August 2003, to ensure that developing countries that lacked pharmaceutical manufacturing capacity may import medicines. In the context of US free trade agreements with developing countries, such as CAFTA, Morocco and Bahrain, the United States had expressly agreed with these trading partners that nothing in the intellectual property chapter affected their ability to take measures necessary to protect public health. Specifically, the United States had confirmed with its FTA partners the understanding that the intellectual property chapter did not "affect the ability of either Party to take the necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency". The United States had also expressly agreed in the context of these free trade agreements that the IPR provisions would not prevent effective utilization of the 30 August 2003 WTO consensus solution allowing developing countries that lacked pharmaceutical manufacturing capacity to import drugs under compulsory licences. In this light, the United States' FTAs with developing countries did not prevent a country from taking the necessary measures to protect public health, or prevent effective utilization of the 30 August 2003 solution.

157. The representative of Brazil welcomed the proposals put forth during the present session, especially the African proposal which was an interesting and positive contribution to the task that the Council had been mandated to carry out by the Decision. The issue at hand was essential to Brazil and had very broad social and humanitarian consequences. While understanding certain delegations' concerns with regard to the quality of drugs, he said that the primary concern was the access to pharmaceutical products, in terms of affordability and availability in the required quantities, that were essential to ensure public health in developing countries. The issue of quality was an issue of a different nature which could be dealt with under other available frameworks.

158. The amendment to the TRIPS Agreement had been mandated in the Decision, and there was a clear difference between the legal status of the Decision and the Chairman's Statement. For his delegation the exercise at hand was to transpose the substance of the Decision into the TRIPS Agreement. The African proposal, being the only one on the table so far, was a good basis for the Council's work and compatible with what was stated in paragraph 11 of the Decision, namely that the amendment would be based, where appropriate, on the Decision. The amendment should not be made through a footnote as this would not bring about the predictability, the legal status and the weight that this subject of utmost importance should have. The amendment should transpose the elements of the Decision, which was self-contained and expressed the consensus among Members. The Chairman's Statement should not be included in any amendment to the Agreement.

159. The representative of India said that there was only one textual contribution on the table, which he welcomed as a good basis for further discussions with the view to completing the amendment exercise by the end of the month. He agreed with those many delegations who had previously said that this should be a technical exercise and that the technical work should be based on paragraph 11 of the Decision. His delegation was prepared to work in any format in order to arrive at the solution by the end of the month.

160. The representative of Kenya expressed his hope that the exercise could be completed by the end of March 2005. He said that Members had frequently been reminded to preserve the minimum standards contained in the TRIPS Agreement. The same should apply when incorporating the solution into the Agreement, namely that the minimum standards that all Members were committed to should be retained. It was for this reason that the African Group had left out some parts of the Decision that were redundant or repetitive. He said that he had not heard a complete rejection of the African Group proposal by anybody, and expressed his surprise at the European Communities' suggestion that the Chairman prepare a text to serve as a basis for discussion. Given that the African

Group proposal was the only one on the table, he would have instead expected the European Communities to submit a position paper, as the United States had done, and then discuss how some of the issues raised could be incorporated into the African Group proposal.

161. He said that there was agreement between Members that the mandate of paragraph 11 clearly provided that the amendment would be based "where appropriate, on the Decision", and not on the Decision and the Chairman's Statement. The African Group proposal fulfilled that mandate as it was based on the Decision. Regarding the comments on the technical nature of the exercise, he said that the African Group had indeed carried out technical work. The approach had been to look at the Decision and at the TRIPS Agreement, maintain the minimum standards and incorporate what the Group had thought was appropriate to accommodate the Decision.

162. He said that Nigeria had already answered many of the questions raised regarding certain specific paragraphs. The issue of whether the Preamble of the Decision was still needed had already been discussed at the last Council meeting. In his view, there was no need to be repetitive and include sub-paragraphs 1(b) and (c). Similarly, the issues addressed in sub-paragraphs 2(a)(i) and (ii) and 2(b)(i) were already covered in the existing provisions of Article 31 of the Agreement, and, hence, there was no need to be repetitive. The same was true of many other provisions, including the one dealing with annual reviews, which would become superfluous once the waiver had been turned into Article 31*bis*. Neither was there any need to mention the issue of regional patent systems; this advice contained in the Decision did not need to become part of the Agreement. Also, the reaffirmation of rights and obligations of Members under paragraph 9 did not need to be repeated as these were already in the Agreement.

163. Accordingly, the amendment should be a technical exercise that would incorporate what was appropriate, not what was inappropriate. If the Decision was to remain as it was today, it could remain unchanged. However, if there was to be a permanent solution in the Agreement, then some of the provisions contained in the Decision would have to disappear in order to maintain the minimum standards that all Members were committed to and to make sure that there was no repetition.

164. The Chairman's Statement was not referred to in the African Group's draft, because it was not mentioned in the mandate of paragraph 11 of the Decision. However, he was not opposed to having another statement read out by the Chairman providing some clarifications, but it should not be part of the permanent solution. Regarding the footnote approach proposed by the United States, he said that the African Group did not regard this as an appropriate way to amend a text and quoted the following passage from a book: "Many writers have argued that the biggest interruption to the reader's train of thought is a footnote. Burying an argument in a footnote and expecting a reader to excavate it is simply inexcusable. If the material in the footnote is relevant or germane to the point one is making, the correct place for it is in the main text". The African Group paper had quoted the most modern English dictionaries in which a footnote was described as providing additional information which was not very important. In contrast, the issue at hand was not merely additional information, but crucial and important to those Members facing this problem and in need of this permanent solution.

165. Regarding the mention in the Chairman's Statement that the solution should not be used for commercial or industrial purposes, he said that, even before the solution had been finalized, the question had been raised how the addressees of the Decision were then to establish capacity. Members with capacity could rely on Article 31 as it was, but those who lacked capacity needed this solution; the amendment should be seen from this angle. Members which were either suppliers or consumers both needed to benefit from the solution. The African Group proposal made some progress in this direction while taking into consideration all the concerns that had been raised. He urged Members to read the proposal over again and see the points which the African Group was trying to raise, even if some of the language used might not have been very clear. It would become apparent that there was no inconsistency between the Decision and the proposed amendment.

166. He said that only such elements that were already in the Agreement had been left out. It was in the nature of any amendment that only new elements would be brought in, as duplication did not add any value. Those Members that were concerned with matters that had been left out would find that all elements were captured in the Agreement, which was a minimum standards agreement. These minimum standards should not be raised but retained at the level that all Members had agreed to.

167. Regarding further work, he said that one option would be to stop the clock and continue consultations to see how far one could advance by the end of the month.

168. The Chairman said that his impression of the discussion was that there had been no new suggestions regarding the way forward. For example, no one had supported the EC proposal that the Chair should work on a neutral draft. However, as he sensed a willingness to continue to work on the issue, he suggested that he suspend the meeting and thus allow for the possibility of reconvening it before the end of March to deal with any potential agreement that might come out of continued informal process.

169. The representative of the Philippines said that he had no objections to the way forward suggested by the Chair and that there was a need to engage in further consultations in whatever shape or form and to intensify the discussions for the purposes of trying to meet the deadline which had been set for March 2005. He noted that a number of interventions had focused on the so-called technical exercise and that a particular delegation had been implying that, rather than adhering to the technical exercise, some Members were in fact attempting, through this amendment process, to retrieve what they had not been able to gain in the waiver decision negotiations. However, many Members, and in particular his delegation, had viewed the negotiations leading up to the adoption of the waiver decision as part of a broader humanitarian context. He said that many Members had in fact been compelled to agree to the terms of the Decision in August 2003 because of this humanitarian element and the need to have something urgently agreed upon by Members, notwithstanding the fact that there had still been some very legitimate concerns arising from certain provisions of the draft Decision. There had been a recognition, that could clearly be seen in the records of the TRIPS Council meeting at which the decision to endorse the draft Decision to the General Council had been made, that Members had agreed to the Decision in the context of this humanitarian concern. Against this background, he believed that it would be inaccurate to characterize some Members' efforts to rectify certain elements which had not been fully agreeable at the time the Decision was adopted as being an attempt to gain back what they had failed to obtain in those waiver decision negotiations.

170. He welcomed the African Group proposal as a very good basis for proceeding with discussions on a possible amendment and found it difficult to appreciate the comments made by certain delegations that the proposed text was not justified because it unravelled the substance of the Decision. Following a paragraph by paragraph assessment of the Decision, it was clear that there was a good basis for the suggestions that the African Group had made. For instance, most if not all the elements mentioned in paragraph 10 of document IP/C/W/440 had been correctly characterized as self-eliminating elements. It was clear that the Preamble would not need to be reflected in an amendment and the same was true for paragraphs 6(ii) and 8 of the Decision, for the very reasons cited in the African Group proposal. He noted that the reference in the tiret of IP/C/W/440 that dealt with paragraph 8 should have been to Article IX:4 of the WTO Agreement, rather than Article X:4. The reference to Article IX in the Decision had been in direct relation to the review requirement for a waiver. Once an amendment had been made into the text of the TRIPS Agreement, Article IX would no longer be relevant but Article 71 of the TRIPS Agreement would be the more relevant provision. Similarly, paragraph 11 of the Decision would no longer be necessary once an amendment was in place. The treatment of paragraph 9 of the Decision might need careful review. The context in which that paragraph had been agreed in August 2003 had been that the waiver decision was not intended to preclude importing countries or trading partners from availing themselves of other flexibilities

existing in the TRIPS Agreement in order to enable the issuance of compulsory licences. To his knowledge, one or two Members had already attempted to do that in practice.

171. Regarding paragraph 11 of IP/C/W/440, he said that most of his delegation's points had already been captured in the justification contained in the various tirets and in the explanatory interventions made by other Members, including Argentina, Kenya and Nigeria. With regard to the last tiret of paragraph 11 of that document concerning paragraph 4 of the Decision relating to re-exportation and the important notion of trade diversion, he reiterated his understanding that paragraph 4 of the Decision was a "best endeavour" undertaking on the part of eligible importing countries. He was concerned that an amendment might not necessarily capture this best endeavour language and, in this context, welcomed the proposed change in the language on trade diversion that had been suggested by the African Group. This was of particular relevance, as in a preliminary review of the legislation put in place by potential exporting countries so far, his delegation had had the impression that if a country had failed to adopt the measures referred to in paragraph 4 of the Decision, such countries might in fact be removed from eligibility as a potential eligible importing country insofar as that particular exporting country was concerned. Although his delegation had noted that this applied essentially to non-WTO Members, it was nonetheless a cause for concern that something which was essentially a best endeavour obligation had now been made a ground for non-eligibility or disqualification from using the paragraph 6 solution insofar as the legislation of a particular country was concerned. He emphasized that this was just a preliminary observation on the basis of a continuing review of this legislation.

172. He said that paragraph 11 of the Decision provided that the amendment would be based where appropriate on that Decision, and not on the Decision and the Chairman's Statement. Nor did it say that such an amendment would be based, where appropriate, on this "solution". There was no reference in any of the documents from the preparatory work or subsequent to the adoption of the Decision that explicitly referred to the Decision and the Chairman's Statement as part of a concrete solution. In that sense, he disagreed with the continuous references to the 30 August solution as necessarily including both the Decision and the Chairman's Statement.

173. Even the explanation in sentence 3 of paragraph 12 of the United States' paper IP/C/W/444 said that the Statement had made a consensus solution possible by addressing and resolving questions concerning aspects of the Decision that had been unclear or had not been addressed. If one was applying the rules of interpretation under the Vienna Convention, then this sentence clearly indicated that, at the very most, the Chairman's Statement provided a merely interpretative context or a supplementary means of interpretation in relation to the Decision, precisely because of the way that this sentence in the submission was couched. Further applying the rules of interpretation, one could make the argument that his delegation did not see and had not been pointed to any particular provision which was unclear in the treaty or in this 30 August Decision. Therefore, if there was nothing unclear in the Decision, then it should be examined within the four corners of that Decision itself and no recourse should be sought to any other context or interpretative context such as the Chairman's Statement.

174. In this respect, he said that he doubted the legal status which was sought to be attributed to the Chairman's Statement and was of the view that any amendment to the TRIPS Agreement necessarily had to exclude the Chairman's Statement as part of the text. Notwithstanding that, his delegation was open to examining the proposal made by the African Group of having the Chairman's Statement read at the time of the adoption of the amendment on condition that all Members could likewise read out their own statements, setting forth their understanding or interpretation of the amendment.

175. The representative of Switzerland said that his delegation was aware of the details and the background which had been underlying the negotiations and ultimately led to the Decision. Against this background and for the sake of a quick implementation of the consensus of 30 August, his

delegation was hesitant to follow an exercise in which the Decision would be examined paragraph by paragraph in order to discuss Members' perceptions on what was and what was not appropriate and what should ultimately be part of the TRIPS Agreement. Such an exercise would risk opening the Pandora's box of restarting the negotiations. If Members were serious in fulfilling their mandate in time, he saw that the only workable way forward was to focus on the technical possibilities of how to integrate the Decision as a whole into the Agreement. In other words, the discussions should concern whether this should be done by way of a footnote, by way of a new Article in the TRIPS Agreement, by way of amending Article 31 or by way of an Annex, or by any other formal way. However, one should avoid discussing any details of the Decision.

176. He noted that different opinions had been voiced regarding the Chairman's Statement. He recalled that the introduction to the note from the Chairman of the TRIPS Council containing the draft statement (JOB(03)/177) read: "I have been working on the text of a Statement to be made by the Chairman of the General Council that would enable all Members to join the consensus on adopting the draft Decision ...". This showed that, without this Chairman's Statement, not all Members could have joined the consensus on adopting the draft Decision. Line four of the second paragraph of that note read as follows: "Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented". The goal of the Chairman's Statement was to give guidance to Members on how to interpret and implement the Decision, and ignoring it now would not be acceptable for his delegation.

177. The representative of Malaysia said that in view of the different opinions of Members there was a need for further consultation and that an informal session to examine in a substantive manner the provisions of the African Group proposal would be useful. She welcomed the new communication IP/C/W/440 as having provided greater clarity to the proposal in document IP/C/W/437 for an amendment to the TRIPS Agreement. The mandate under paragraph 11 provided that the amendment should be based where appropriate on the Decision and the African Group proposal was based on this premise. Regarding the form of the amendment, her delegation agreed with the arguments in the African Group proposal against a footnote and supported an amendment of the text of the Agreement. Regarding modifications to the Decision, she noted that provisions that no longer served their original purpose in the context of the amendment should be discussed further.

178. Regarding the Chairman's Statement, her delegation was opposed to upgrading the legal status of the statement that accompanied the Decision by incorporating it as part of an amendment. It also opposed having a Chairman's Statement read as part of the adoption of any amendment, because such an amendment was already a substantive change to the TRIPS Agreement and there was no need for a Chairman's Statement to reinterpret that amendment. This would only add further legal uncertainties to an amendment.

179. The representative of the United States agreed with Switzerland that a paragraph by paragraph approach would re-open individual issues, which would be contrary to the current objective of preserving the entire consensus reflected in the Decision and the Chairman's Statement. He said that his delegation was willing to participate in whatever consultations the Chair deemed appropriate.

180. Noting the positions of Switzerland and the United States regarding the paragraph by paragraph approach, the representative of Kenya suggested that they propose an alternative way of establishing which paragraphs were appropriate and which were not, as paragraph 11 clearly said "where appropriate" and that could not be ignored. Commenting on Switzerland's statement on the background of the negotiations, he said that Members had been prevailed upon to accept the statement and that the explanation that had been given at that time was not the same as was being given today.

181. The Council agreed to suspend the meeting, with the possibility that it be reconvened if necessary, so as to allow for continued consultations with a view to meeting the March 2005 target date.

182. Reconvening the meeting on 31 March, the Chairman referred to the further consultations he had held to see whether progress could be made towards a TRIPS Council recommendation to the General Council by the end of March on an amendment to the TRIPS Agreement to replace the provisions of the paragraph 6 Decision. These consultations had showed a continuing divergence of views among delegations on some key issues, especially relating to the content of the amendment. Since then, he had been contacted by some delegations and, in the light of their request, had reconvened the suspended formal meeting of the Council in order to provide an opportunity for delegations to make statements on TRIPS and public health.

183. The representative of Rwanda, speaking on behalf of the African Group, said that the President of the United States, referring to the case of Terri Schiavo who had been in a vegetative state for the last 15 years, had said that "where there are serious questions and substantial doubts, our society, our laws, and our courts should have a presumption in favour of life. It should be our goal as a nation to build a culture of life". The dedication "to build a culture of life" should be stronger, more urgent and immediate in the TRIPS Council which had been mandated to find a permanent solution on how to ensure a sustainable supply of essential generic medicines to the millions of people dying every day, particularly in Africa, for not having access to life-saving affordable medicine because they lacked the manufacturing capacity. Unfortunately, this dedication and determination seemed to be lacking. Four years had passed since Members had recognized the problem faced by WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector in making use of compulsory licensing under the TRIPS Agreement, and the African Group was disappointed that Members had not moved closer to finding a permanent solution to this problem. The African Group had submitted a proposal on how to incorporate the temporary waiver into the TRIPS Agreement. It had provided a detailed explanation about the proposed amendment. It had also explained that certain parts of the Decision were redundant and should not form any part of the permanent solution. However, it appeared that some Members were not engaging constructively in this discussion. For instance, they acknowledged that some parts of the waiver were redundant but to date no concrete proposal had been tabled by any of them.

184. She said that, at the time the Decision had been agreed to, the African Group had proposed many options that would have allowed countries to export and import affordable generic medicines to satisfy the public health needs of people worldwide. However, it had faced a lot of pressure from some Members which had imposed many conditions that were difficult to meet. Finally, after months of discussion and debate, an interim solution in the form of a waiver of Article 31(f) and (h) had been agreed to by Members. The African Group and many other developing and least-developed countries had not been entirely happy with this solution and this had been made very clear during the TRIPS Council meetings. The Group had agreed to this "interim solution" on the precise understanding that it was only an interim solution, while discussions to find a permanent solution would continue. This understanding was reflected in paragraph 11 of the Decision which stated: "The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view of its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision". The ordinary meaning of the sentence "the amendment will be based, where appropriate, on this Decision" indicated that it had never been the intention of Members to use the entire Decision as the amendment. Only those parts of the Decision that were appropriate were to be used.

185. With regard to the Chairman's Statement, it was important to understand the circumstances in which the Statement had come into being, so that it could be put in its proper context. The reading of the Chairman's Statement, when the Decision was adopted, had been more of an attempt to provide comfort language to assuage the concerns of some pharmaceutical industries that generic

manufacturers would gain a strong foothold in the pharmaceutical market. During the informal TRIPS Council meetings, some developing and least-developed countries' delegates had expressed their reservations over the content of the statement, which was a clear indication that this statement had never been intended to form any part of the permanent solution.

186. The main reason why those countries with reservations had agreed to go along with the Chairman's Statement had been because they had felt an urgent need to make a contribution to the success of the Cancún Ministerial Conference. WTO Members might recall that there had been a strong feeling at that time that a solution, even if it was an interim one, had to be concluded before the Cancún meeting so that the meeting could focus on other issues and thus have a better chance of success. It had been felt by all that a Chairman's Statement would help facilitate a quick conclusion of an interim solution. But it had also been the understanding that this would only be an interim solution, and that a permanent solution would require more careful consideration, taking into account all the aspects, including how the mechanism chosen could be operationalized in practice.

187. She said that the Chairman's Statement should thus be seen as a facility that served a particular purpose at that time, mainly to meet the deadline of having a temporary settlement before the Cancún meeting. However, the circumstances had been temporary and they no longer existed. In line with the context in which the Chairman's Statement had come into being, the Decision that had been agreed to in document IP/C/W/405 did not make any reference to the Chairman's Statement. It was only later that a footnote referring to the Chairman's Statement had been added, without the express consent of Members. Indeed, he said that the African Group was puzzled as to how that footnote came to be added and that it wished to have a clarification on this. Moreover, it had to be put on record that it had been added without the consent or consensus of Members. Thus, the African Group which made up a large portion of the WTO’s Membership could not and would not accept an interpretation of paragraph 11 that said that the Decision and the Chairman's Statement in its entirety should form the amendment.

188. She recalled Members' commitment in the Doha Declaration to interpret and implement the TRIPS Agreement "... in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all". The African Group was not convinced that the Decision together with the Chairman's Statement as it stood at that time would fulfil the commitment to protect public health and promote access to medicines for all. Indeed, concerns had been raised by policy makers in African countries that the "interim solution" as it presently stood could pose problems and obstacles to the realization of the goal of access to affordable medicines for all.

189. An African regional workshop on Patents and Access to Medicines organized by the African Union Commission and attended by policy makers from the health ministries and patent departments of 35 African countries had discussed the issue and had expressed concerns on the workability of the "interim solution". It had also supported the position of the African Group in the WTO on its approach to seeking a permanent solution. A Statement adopted by participants at the workshop stated:

> "Participants stressed that the issue of the effects of patents on access to medicines is very crucial for the African region which among all continents in the world is the poorest and its people are most affected by serious diseases, and therefore the need for access to affordable effective medicines is a must. Deaths attributable to HIV/AIDS alone in 2004, estimated at 2.5 million, are equivalent to ten times the devastation caused by the Tsunami of December 2004. It is urgent that all countries act individually and collectively to remove all obstacles to securing sustainable supplies of essential medicines for the people of the region."

190. In relation to the Decision, it stated that "this decision imposes several conditions on importers and exporters who wish to make use of the waiver, which may affect the ability for the mechanism to meet its goal", which was the supply of essential generic medicines to countries with insufficient or no manufacturing capacity. The Statement further called for "a more appropriate 'permanent solution' that revises TRIPS and that removes the Article 31(f) constraint without placing new constraints so that the export and import of generic medicines can be smoothly facilitated". The representatives at this workshop had also expressed their support for the position and efforts of the African Group in the WTO.

191. From the statement, it was evident that policy makers at the national level considered that the interim solution contained shortcomings that might affect the operational effectiveness to meet the goal of supplying affordable medicines, that an appropriate permanent solution was urgently required, and that they supported the proposal submitted by the African Group for the amendment. She said that the issue at hand was critical to the African continent and people worldwide. Members could not and should not delay this matter any longer. Although an interim mechanism existed, it had its shortcomings which might account for the fact that it had not been used up to now. In addition, this waiver was subject to review and could be terminated at any time. The African Group thus sought a solution that was permanent, sustainable, secure and predictable. It had put forward a proposal based on the appropriate elements of the Decision and had already explained that proposal in detail. The Group now sought the understanding and agreement of other Members.

192. The modality for achieving a permanent solution was expressly spelled out in paragraph 11 of the Decision. Therefore, the Group requested all Members of the WTO to share its interpretation of paragraph 11 of the Decision, and to engage constructively with the intention of resolving expeditiously the Doha Declaration's paragraph 6 problem, in favour of supplying affordable medicines to those who were most in need. Finally, the Group was of the view that a permanent solution was within reach if Members acted in accordance with the letter and spirit of paragraph 11. She expressed her hope that the consultations to be undertaken by the new Chairman of the TRIPS Council, would finalize the amendment so that a Decision could be adopted at the General Council meeting to be held in May 2005.

193. The representative of Zambia, speaking on behalf of the LDC Group, said that the group agreed with the statement of the African Group. He said that, at the height of the discussion on how to resolve the paragraph 6 problem, major developed country Members had made a number of promises to other Members in order to obtain their support for the Decision and the Chairman's Statement. His delegation had been informed that the Decision was intended to be only an interim solution and that discussions towards finding a permanent solution in the form of an amendment of the TRIPS Agreement would continue. The understanding of Members on how these discussions should proceed was reflected in paragraph 11 of the Decision. The Group's understanding was that the intention had never been to regard the Decision as a consensus solution and that it had been, and remained, only an interim solution. Only appropriate elements rather than the entirety of the Decision should be adopted as part of the amendment.

194. He said that the group had reservations over the content and the status of the Chairman's Statement. There had never been an agreement or any kind of understanding among Members that all the elements of the Chairman's Statement should form part of the amendment and, therefore, Members should be guided by paragraph 11 of the Decision. He said that the view held by some Members, that certain groups of countries wished to re-open the debate that had conclusively ended in August 2003, had no basis because it was not supported by paragraph 11 of the Decision. He called upon those Members to refrain from making statements that misinterpreted the circumstances that had been prevailing and the understanding that had been reached at the time of the adoption of the Decision. The African Group proposal, consistently with paragraph 11, had selected the most appropriate elements of the Decision to form the amendment. He urged Members to engage positively to discuss the proposal or to submit proposals that would build on it constructively. The Group called upon the Membership to come up with a comprehensive and predictable solution to this matter and underlined the urgency and the importance of the issue of TRIPS and access to medicines for all vulnerable constituencies. For his group, this was not a matter of procedural debate, but an emergency with social and economic implications on which the well-being and lives of millions of its people depended. It was, therefore, a matter of life and death for many countries to urge the Members to continue working for a permanent solution for adoption by the General Council meeting in May 2005.

195. The representative of Argentina said that his delegation had no commercial interests or companies behind it. It was seeking a solution to help save the lives of millions of people in line with the Declaration of 2001. The solution that had been reached in 2003 was an interim solution and he was concerned about the lack of agreement over the last two years in trying to solve this urgent question. There was a danger that this interim solution would become the permanent solution. Although the Doha Declaration on TRIPS and Public Health was distinct from the other Doha Declarations, there was an undeniable link between them and it would be naïve to think that the Doha Round could end in a satisfactory manner unless a satisfactory solution was found to the question raised in the Declaration on health. He urged all delegations to continue working constructively to urgently find a solution and respond to the goal specified in the Declaration on TRIPS and Public Health.

196. The representative of Benin, speaking on behalf of the ACP Group, said that the group associated itself with the statements by the African Group and Zambia. He underscored the importance of access to medicines, particularly for those countries with no or insufficient production capacity. The Decision was intended to be an interim solution until such a time as a permanent one could be reached. He supported the African Group's suggestion on how to move forward and urged Members to work with a view to reaching a useful and helpful solution by the May meeting of the General Council.

197. The representative of Cuba agreed with Rwanda, Zambia and Benin that it was urgent that an adequate Decision be taken on this issue. The Decision was an interim Decision. It was clear that not all aspects of it could be taken into consideration in an amendment. She urged all Members to engage in a constructive and positive manner in consultations to find an appropriate and adequate solution to this problem.

198. The representative of Kenya said that the statements by the coordinators of the African Group and the LDCs were indicative of the journey that had been covered so far since 2001. Just as Britain respected its written and unwritten constitution, Africa respected the written and unwritten promises that had been made behind the scenes and that was why they had accepted the solution. However, those promises seemed to have evaporated as soon as the exercise to amend the TRIPS Agreement had begun, and they needed to be brought back to the table so that this exercise could be concluded immediately. Since one could not go back in time and revise the damage already done, one should at

least take action at the present time to make things better for the future and make every effort to conclude the exercise by May.

199. The representative of Brazil said that a constructive and a positive attitude should be shown by all to achieve a quick consensus regarding a solution for an amendment. The African Group proposal had received widespread support from the African countries, the LDCs as well as the ACP countries and he welcomed it as a good basis for further work. He agreed with their interpretation of paragraph 11 of the Decision. The Decision was an interim solution and the Chairman's Statement was not part of the mandate for the amendment. His delegation was willing to engage constructively to achieve a permanent solution to this pressing and urgent humanitarian issue.

200. The representative of India said that he shared the disappointment expressed by Rwanda that no final decision on the proposed amendment to the TRIPS Agreement could be reached by the end of the deadline. His delegation had already expressed its support for the African proposal in previous meetings and continued to give full support to any discussions at any time that would enable the Council to reach a decision on this matter.

201. The representative of the Philippines said that his delegation fully supported the statement made by Rwanda on behalf of the African Group and expressed his regret that certain Members had refused to engage constructively in discussing a permanent solution through an amendment of the TRIPS Agreement. He reiterated that the wording of paragraph 11 – "the amendment will be based, where appropriate, on this Decision" – did not mean a simple adoption or transposition of the Decision into an amendment, nor did it mean the adoption or transposition of the Decision together with the Chairman's Statement. Despite certain delegations' insistence on using the phrase "August 30 solution" rather than "August 30 Decision", paragraph 11 clearly referred to the Decision only. There was no reference in the Decision nor any consensus in the TRIPS Council discussions subsequent to the Decision that the amendment exercise would be a simple technical exercise, as a few delegations continued to insist.

202. Viewed in the context of Members' interventions in the TRIPS Council's meeting of 28 August 2003 approving the Decision, and subsequently in the General Council meeting of 30 August 2003, it was clear that Members like the Philippines had agreed to the Decision on the premise and in the belief in the word of the then Chair as well as certain key players in these negotiations that their concerns would be addressed or could be rectified during the amendment process. Members had acquiesced with such an appeal for approval at that time, given the urgency for a need to establish a mechanism to address the problems of developing countries with no or insufficient manufacturing capacity in the pharmaceutical sector. To be confronted now with a situation where it was incumbent upon them to show that the amendment would have to include certain substantive rectifications and to be told that these were not possible in this amendment process was something he found difficult to accept. If the WTO was keen on confidence-building, then it was incumbent upon the trading partners, on whose word his delegation had trusted before, to live up to that word.

203. He said that it was not only the General Council Chairman's Statement that had provided context for the Decision. A number of statements, including one by his delegation, had been read out at the TRIPS Council meeting and at the General Council meeting in August 2003 to set forth Members' understanding or interpretation of both the Decision and the Chairman's Statement, and these should equally be seen as providing an interpretative context for the Decision. He reiterated his full support for the African Group's suggestion for the incoming Chair of the TRIPS Council to conduct extensive consultations to reach a permanent solution for an amendment to the TRIPS Agreement before the May General Council meeting.

204. The representative of Sri Lanka said that, as his country had insufficient manufacturing capacity for pharmaceutical products, it was particularly concerned with finding a permanent solution. AIDS had caused twice as many people to die than the tsunami catastrophe. In 2003, the adoption of the Decision had triggered praise from the press that the WTO was capable of responding to humanitarian needs. Further delay in finding a permanent solution would not live up to that public view and he, therefore, urged Members to agree on the necessary amendment to the TRIPS Agreement by May.

205. The representative of Lesotho said that, although her delegation was aware that there was some pressure for commercial opportunities from pharmaceutical companies in developing countries, the dominant pressure to amend the TRIPS Agreement came from the people dying of AIDS every day. She asked Members to show compassion.

206. The representative of Pakistan said his delegation supported the statement by the African Group. The solution reached in August 2003 was only an interim solution and the Chairman's Statement was not part of that solution. Had the solution been intended to be permanent, it would have clearly stated it and would not have used formulations like "where appropriate" and "where the interim solution will cease to operate when provisions for permanent solution are in place". These words indicated clearly that there had been no consensus on this being a permanent solution at the time. Rather, the background to the negotiations had been as Kenya and the African Group had described it. He urged Members to engage in a positive dialogue and come to a solution along the lines of the African proposal.

207. The representative of Uganda said that he shared the interpretation of paragraph 11 by the African Group, the LDC Group and the ACP Group and urged Members to work towards a solution. He informed Members that demonstrations on that issue had taken place in Uganda the previous week and that the Indian High Commission had been requested that India should not take any decision that would have repercussions for the people living with AIDS.

208. The representative of Rwanda thanked all Members that had supported the African Group proposal and said that this support was a clear indication of Members' will to find a solution prior to the General Council meeting to be held in May.

209. The representative of Peru said that his delegation supported the statement made by the African Group that a rapid and effective solution to the concerns should be found. He noted that delegates at the Commission on Human Rights in session at the United Nations had also expressed their commitment in the area of public health and urged Members to find a solution also in this forum.

210. The representative of the United States said that his delegation remained committed to reaching a consensus on an amendment to the TRIPS Agreement that fully preserved the solution of 30 August 2003. This solution represented a comprehensive and balanced system to allow those that lacked the capacity to manufacture drugs, to import the drugs that they needed without these drugs being diverted to other markets. The agreement reached on 30 August 2003 had garnered support from all WTO Members and had met their objectives. Its transformation into an amendment should be a technical exercise and substantive issues should not be re-opened. Therefore, his delegation did not consider that any substantive provisions of the Decision would be inappropriate for incorporation into the amendment. His delegation was not familiar with promises that may have been made or broken or whether these were relevant, and expressed its concern over the presence of such allegations without further clarity. His delegation's recollection of this process, in which the United States' Ambassador had been fully engaged, was that the range of benefits and viewpoints had been reflected in the solution, and that without this balance a consensus would not have been possible.

211. He said that the task of agreeing to an amendment that preserved all aspects of the 30 August 2003 consensus would be very difficult if Members were seeking to change the content of that solution. His delegation disagreed with the characterization of the Chairman's Statement made at the present meeting and with the attempt of some Members to re-characterize the circumstances under which the consensus had been agreed upon. The Chairman's Statement represented key shared understandings of Members. It was an integral part of the solution that had been reached and had to be preserved in the amendment. The United States strongly supported the 30 August 2003 solution and noted that the waiver was currently in force and would remain in force until the amendment process was completed. This had permitted Members such as Canada, Switzerland, Norway, the European Communities and potentially others to act to implement the solution and the United States also encouraged and supported Members to make effective and appropriate use of that solution.

212. The representative of Kenya said that, while there were no records of the informal process that lead to the Decision, one could still trace some of the statements made during the informal consultations as these had been attached to the minutes of the General Council meeting in document WT/GC/M/82. For instance, the Kenyan Ambassador had said in her statement that "[w]e are also comfortable in the knowledge that it will not affect in any way our intention to improve our manufacturing capacity, which is our medium - as well as long-term objective, and that this is a temporary solution which will come to an end after the permanent solution envisaged in paragraph 11 of the draft Decision is in place". Similar statements had been made by Venezuela, Nicaragua, Senegal and others. It could also be seen from the statement by Canada at the time that the issue had not only been of interest to developing countries. Canada's Ambassador had among others extended his thanks to the African countries with the words: "the final thank you goes to all my African colleagues. It was their countries and their citizens who were always recognized as the primary beneficiaries of the Declaration on TRIPS and Public Health. It was their people who had the most need. And yet, they have demonstrated remarkable patience with us, on such a 'life and death' issue. I am not sure many of us, in similar circumstances, would have acted as honourably". The first paragraph of the opening statement by the African Group was a testimony to what the Canadian Ambassador had said at that time.

213. Members should not forget the degree of activity that had taken place behind the scenes in the few days before and right up to the meeting in which the Decision had been taken. The promises that had been made were not in the Decision, but some Members had been told that all their concerns and problems could be addressed during the amendment process. His delegation had even prepared a statement which it had been prevailed upon by other Members not to issue. If Members were still doubting this background, he could produce this statement as proof and disclose the details of the topics discussed behind the scenes and in capitals at the time of the Decision. This issue was as urgent today as it had been four or five years ago when it had been raised by the African Group. It had not subsided, but it had actually intensified, and other regions were at an even bigger risk than Africa. This solution would not just be a solution for Africa, it would be a solution for the whole world. The material was in front of Members, and their work was cut out in paragraph 11 of the Decision. He urged Members to work on that basis to put a solution into place by May.

214. The representative of Switzerland said that his delegation remained committed to the process of implementing the Decision and that the details of its position and proposals were contained in its statement of 8 March. It remained key to his delegation that any implementation solution would have to reflect the entirety of the substance of the consensus and the solution found by the Membership on 30 August 2003. Only a purely technical amendment could faithfully translate that consensus which had only been achieved after a long and difficult negotiation process and which represented a delicate balance of interests of Members. It had to be taken into consideration that a number of Members, including Switzerland, were presently revising their national laws in order to quickly and faithfully implement the paragraph 6 solution as adopted by the General Council. Any re-opening of the consensus found by the General Council would seriously undermine these national revision processes

and would endanger, if not prevent, a transparent and uniform use of compulsory licences for the export of pharmaceuticals under the terms and conditions of paragraph 6 mechanism.

215. For reasons of legal security, expeditiousness and efficiency, Switzerland had proposed the footnote approach as the form for the implementation of the paragraph 6 solution in the TRIPS Agreement as a practical and straightforward solution. The General Council Chairman's Statement had been part of the consensus found on 30 August 2003 and, therefore, was an integral part of the paragraph 6 solution that had been found that day. Accordingly, the statement had to be reflected adequately in the amendment. It was the view of his delegation that the matter should be put on the agenda of the next session of the TRIPS Council for further discussion.

216. Referring to his delegation's earlier intervention under this agenda item, the representative of the European Communities said that his delegation remained committed to finding a solution in line with paragraph 11 of the Decision and ready to engage in whatever process was deemed appropriate. While being ready to join others in working towards the May General Council meeting as the target, he noted that there would be a lot of ground to cover in a short time. He shared the view that the link to the Chairman's Statement needed to be preserved in any solution without upgrading its legal status, and said that this was an important point which could not be ignored. He disagreed with the suggestion that the Chairman's Statement and other statements made at the same General Council meeting had the same relevance to the amendment process. He said that a constructive and perhaps at times even creative approach was needed, and recalled that that his delegation had expressed a view in the past as to how the process might be conducted, which remained its view.

217. The Chairman expressed his personal regret that he was leaving the Chair without having been able to find a solution. He said that there appeared to be a general willingness among Members to continue consultations in the period until the 26-27 May General Council meeting with a view to enabling the General Council to take action at that time, as suggested by the African Group, and that Ambassador Choi Hyuck had signalled his preparedness to undertake the task.

218. The Council agreed to proceed as suggested by the Chair.

219. Regarding the clarification sought by the representative of Rwanda on the asterisked note in document WT/L/540, a representative of the Secretariat clarified that this asterisked note was not part of the legal text of the Decision. Its purpose had been to provide factual information about the way the Decision had been adopted in the belief that this would be found helpful. If there were Members who did not find this information helpful in the text of the Decision as circulated, and maybe even found it confusing, one course of action might be to re-issue the Decision without this note. Of course, doing this would not affect the status of the Chairman's Statement and its link to the Decision; these were governed not by the note to document WT/L/540 but by the action that had been taken by the General Council at its meeting of 30 August 2003, as recorded in the minutes of that meeting.

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

220. The Chairman recalled that, at its meeting in December, the Council had taken up, pursuant to paragraph 2 of the decision on the "Implementation of Article 66.2 of the TRIPS Agreement", its second annual review of developed country Members' reports on their implementation of Article 66.2 (circulated in document IP/C/W/431 and addenda). Since that meeting, an additional report had been received from Norway (subsequently circulated in document IP/C/W/431/Add.6).

221. No statements were made under this agenda item.

J. TECHNICAL COOPERATION AND CAPACITY-BUILDING

222. The Chairman recalled that, on 14 June 2001, the WIPO and WTO Secretariats had launched a Joint Initiative on Technical Cooperation for Least-Developed Countries. Since then, the WTO Secretariat had kept the Council informed about the implementation of the Joint Initiative.

223. A representative of the WTO Secretariat said that, since the Council's last meeting, the WIPO and WTO Secretariats had organized, under the Joint Initiative, a joint national seminar on TRIPS in Niamey, Niger in December 2004. Two activities specifically addressed to LDCs were foreseen for the first half of the year 2005, namely a national seminar in Lesotho, that had originally been planned for December but postponed at the request of the Lesotho authorities, and another national seminar in Chad. As part of the WTO Technical Assistance Plan for 2005, the Secretariat was organizing four regional or sub-regional workshops which also covered LDCs. The first of them had been held in Fiji in January 2005 in response to requests from Pacific island countries. The remaining three were planned to be held in Gabon for French-speaking African countries at the end of May, in Zambia for English-speaking African countries at the end of July, and the last in one of the Caribbean countries later in the year.

224. He also drew attention to the second "WIPO-WTO Colloquium for Teachers of Intellectual Property Law" that was being organized jointly by the two organizations from 27 June to 8 July 2005. It was part of each of the two Organizations' capacity building programmes, aimed, in this case, at enhancing the capacity of universities and teachers in developing countries with respect to the activities and instruments of WIPO and the WTO. Only 20 places were available for the colloquium. Information on the colloquium, including online application forms, was available from the websites of WIPO and the WTO. He suggested that interested Members might wish to encourage eligible intellectual property teachers within their countries to apply before the deadline of 15 April 2005.

225. A representative of WIPO thanked the Government of Niger for its cooperation and hospitality during the seminar in December.

226. The Council took note of the statements made.

K. REQUEST FROM MALDIVES FOR AN EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT

227. The Chairman recalled that, at its last two meetings, the Council had had before it a request from the Maldives for an extension of the transition period under Article 66.1 of the TRIPS Agreement for a further five years (IP/C/W/425). The Council had agreed that consultations be held on this request, and that the arrangements for these be coordinated between the Chair of the TRIPS Council and the Chair of the CTD.

228. Since then, the delegation of the Maldives had not been able to attend the meetings of the CTD and there had, therefore, not yet been an opportunity to organize consultations on this matter. At the meeting of the CTD held on 22 February 2005, the Chair of that body had informed Members that the Maldives had provided a written communication to the Committee stating that it wanted the UN to re-examine its position concerning the recent decision to graduate the Maldives from LDC status because of the devastating effects of the December tsunami on its economy (WT/COMTD/52). The CTD had agreed to revert to the matter at its next meeting scheduled for 11 May 2005.

229. The Chairman informed Members that, on 20 December 2004, the United Nations' General Assembly had adopted a decision on "Smooth transition strategy for countries graduating from the list of least-developed countries". Paragraph 3(e) of that decision provided that "[t]hree years following the decision of the General Assembly to take note of the recommendation of the Committee for

Development Policy to graduate a country from the list of least developed countries, graduation will become effective; during the three-year period, the country will remain on the list of least developed countries". The General Assembly had then taken note of the recommendation of the Committee for Development Policy to graduate Maldives from the group of least-developed countries. Maldives would thus retain its LDC status until 20 December 2007.

230. Given this three-year period in which the Maldives would retain its LDC status, there was no issue about it benefiting from the TRIPS transition period until the end of year 2005. The Chairman suggested, therefore, that the Council consider later in 2005 what action it should take in response to the Maldives' request for a five year extension of its transition period under the TRIPS Agreement, taking into consideration any further developments concerning the Maldives' status as an LDC and any further discussions in the CTD context on this matter.

231. The Council so agreed.

L. NON-VIOLATION AND SITUATION COMPLAINTS

232. The Chairman recalled that the General Council decision of 1 August 2004 on the Doha Work Programme provided, under the title "Other elements of the Work Programme", that the moratorium on non-violation and situation complaints covered by paragraph 11.1 of the Doha Ministerial Decision on Implementation-Related Issues and Concerns had been extended up to the Sixth Ministerial Conference. This matter had been on the agenda of the last Council meeting and had been discussed, *inter alia*, on the basis of an updated Secretariat summary note on the points raised in the Council's substantive discussion of this matter so far (IP/C/W/349/Rev.1).

233. The representative of Korea said that his delegation shared the view of the vast majority of Members that non-violation and situation complaints were a concept primarily intended for market access agreements. Their application in the context of the TRIPS Agreement would introduce a degree of uncertainty, which was undesirable for the sound operation of any intellectual property regime. He noted that the moratorium on non-violation and situation complaints had been extended several times and that such repeated extensions, without reaching a conclusion on the applicability of such complaints, undermined the stability of the TRIPS system. He hoped that Members would be able to reach consensus at the Sixth Ministerial Conference to the effect that non-violation and situation complaints were not applicable to the TRIPS Agreement.

234. The representative of Peru said that his delegation believed that it was time to put paid to the issue of the moratorium on non-violation and situation complaints and that this issue could be wrapped up at the Hong Kong Ministerial Conference.

235. The representative of Ecuador said that he agreed with Korea. He reiterated his delegation's position reflected in documents submitted to the Council, namely that non-violation and situation complaints were intended for situations other than those existing under the TRIPS Agreement. He hoped that the legal uncertainty resulting from the moratorium could soon be resolved and the item removed from the agenda.

236. The representative of India, supporting the statements made by Peru and Ecuador, recalled that the three delegations, together with a number of other Members, had co-sponsored document IP/C/W/385 circulated in October 2002. He cited from paragraph 11 of document IP/C/W/349/Rev.1 which read: "It has been argued that applying the non-violation remedy under TRIPS would provide security and predictability and help ensure that the TRIPS Agreement's flexibility is not misused in order to avoid legitimate obligations." Commenting on the use of the term "legitimate obligations" in this sentence, he said that the flexibilities of the TRIPS Agreement were a part of the balance of rights and obligations within the TRIPS Agreement and that these legitimate flexibilities were parts of

legitimate rights. When shifting from violation complaints to non-violation complaints, panels and the Appellate Body had usually referred to legitimate expectations arising not from *obligations* but from legitimate *expectations*, as the term had been understood in the jurisprudence. Therefore, he did not believe that any further security and/or predictability was required to be provided in respect of the TRIPS Agreement's flexibilities or possibilities to use these flexibilities, which could not and should not be characterized as misuse of legitimate obligations.

237. The representative of Malaysia, joining the delegations of Korea, Peru, Ecuador and India, reiterated her delegation's position that non-violation and situation complaints were not applicable to the TRIPS Agreement. There were no legal or other facts that showed any need for non-violation remedies in the TRIPS Agreement. Making non-violation complaints available would impose systemic difficulties in the operation of a predictable and rules-based multilateral system, because non-violation complaints would introduce elements of legal uncertainty. Their existence would result in and compel actions that went beyond the TRIPS Agreement as a minimum standards agreement. The Secretariat summary note referred to a long list of reasons given by Members why non-violation and situation complaints should not be applicable to the TRIPS Agreement. She hoped that this chapter of discussions could be closed as soon as possible.

238. The representative of the United States said that his delegation continued to consider that non-violation complaints were fully appropriate in the TRIPS context and expected the moratorium to expire at the Sixth Ministerial Conference. In response to the comments from other delegations, he said that the application of NVNI complaints to the TRIPS Agreement would not upset the balance of rights and obligations in TRIPS. It was unambiguously clear that, in Article 64 of the TRIPS Agreement, the provisions of Article XXIII 1(b) and (c) of GATT 1994 had been contemplated in the context of the TRIPS Agreement and that that was an integral part of the final package negotiated during the Uruguay Round. The objective of NVNI complaints was to discourage actions that might evade obligations without directly violating them. No clear reason had been provided why the TRIPS Agreement should not benefit from that objective. The failure to allow this possibility in connection with the TRIPS Agreement could invite Members to seek creative ways to avoid TRIPS obligations. The United States remained willing to discuss how the NVNI remedies applied to the TRIPS Agreement. In this respect, Article 26 of the DSU was helpful and provided important guidance for Members when considering NVNI complaints under TRIPS. The United States felt that Article 26 of the DSU provided all the necessary assurances and safeguards for Members to handle any disputes alleging non-violation nullification and impairment under the TRIPS Agreement and to prevent any abuse of the dispute settlement process.

239. The representative of the Philippines associated himself with the statements by Malaysia, India, Peru and Ecuador calling for the closure of the chapter on the applicability of non-violation complaints under the TRIPS Agreement. It would be inappropriate if non-violation complaints were deemed applicable in the TRIPS context after the Sixth Ministerial Conference, as the TRIPS Council had not reached any conclusion on the scope and modalities of the applicability of such complaints.

240. The representative of Canada said that she shared the position of most other Members, namely that NVNI complaints should not apply in the context of the TRIPS Agreement. The reasons for this had been elaborated in several written submissions in recent years. Agreeing to now apply NVNI complaints under the TRIPS Agreement would shift the balance of rights and obligations that Members had maintained in the TRIPS Agreement since the Uruguay Round. The onus was on the Members proposing the applicability of NVNI complaints to explain why the Council should agree to change that status.

241. The representative of Brazil, agreeing with the statements made by Canada, India, Malaysia, the Philippines, Ecuador, Peru and Korea, said that he expected the Hong Kong Ministerial

Conference to agree, in accordance with the opinion of the overwhelming majority, that non-violation and situation complaints did not apply in the context of the TRIPS Agreement.

242. The representative of Argentina said that, like the delegations of Brazil, the Philippines, Malaysia, Ecuador and the Dominican Republic and the majority of the Council, she hoped that this issue would be solved along the lines of the proposal presented by her and certain other delegations in document IP/C/W/385.

243. The representative of Japan said that the Council should continue to study and discuss the scope and modalities of non-violation complaints in order to ensure the predictability of their application.

244. The representative of the European Communities said that his delegation considered that non-violation complaints should not be applicable in the TRIPS context.

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

M. SPECIAL AND DIFFERENTIAL TREATMENT PROPOSALS REFERRED TO THE COUNCIL

246. The Chairman said that, in its Decision on the Doha Work Programme of 1 August 2004, the General Council had recalled Ministers' decision in Doha to review all special and differential treatment provisions with a view to strengthening them and making them more precise, effective and operational, and recognized the progress that had been made so far. As regards all those WTO bodies to which proposals in Category II had been referred, the General Council had instructed them to expeditiously complete the consideration of these proposals and report to the General Council, with clear recommendations for a decision, as soon as possible and no later than July 2005. This matter had been on the agenda of the last Council meeting, where the Council had had before it an informal Secretariat note summarizing the Council's work so far on the Category II proposals on special and differential treatment referred to it (JOB(04)/164). No comments had been made on the item at that time.

247. The representative of Kenya requested clarification of the status of the two proposals that Members had been discussing under this item at previous meetings. He said that he had been under the impression that the Council had already worked on one proposal dealing with exclusive marketing rights and had forwarded it to the relevant body and that it was only the LDC's proposal on extension that was still pending.

248. A representative of the Secretariat responded that, as described in Document JOB (04)/164, there were two proposals, the second of which had two elements. With regard to one of these elements contained in the second proposal, agreement had been reached amongst participants and that proposal had been forwarded at that time by the Chairman of the TRIPS Council to the Chairman of the General Council to be included in the package that was going to Cancún. As no action had been taken at Cancún, it remained a text that had been agreed at the level of the members of the TRIPS Council, but which had not yet been formally acted upon and put into force at the final level.

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

N. INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

250. The Chairman informed the Council that panel reports on *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs,*

complaints by the United States and Australia, were expected to be circulated on 15 March in documents WT/DS174/R and WT/DS290/R, respectively.

251. The representative of the European Communities said that his delegation wished to raise the issue of compliance by the United States with DSB rulings on intellectual property matters. While it was the duty of the Dispute Settlement Body to keep under surveillance the implementation of recommendations and rulings in dispute settlement cases, the TRIPS Council nonetheless had a clear interest in following developments in this area from a broader perspective, as clearly provided by Article 68 of the TRIPS Agreement. He drew Members' attention to the fact that there were two outstanding disputes concerning intellectual property matters, both of them concerning US laws, in relation to which the United States was under an obligation to bring its legislation into conformity with the TRIPS Agreement. The first case concerned Section 110(5)(B) of the US Copyright Act, which a WTO panel had found in 2000 to be inconsistent with the US obligations under Section l, Part II of the TRIPS Agreement. The United States had been granted a period of one year to comply with the ruling, i.e. until July 2001. However, the US Copyright Act had still not been amended.

252. The second case concerned a piece of US legislation affecting the renewal and enforcement of certain trademarks and trade or commercial names. This legislation had been condemned more than three years previously. On several occasions, the European Communities had taken into account the difficulties of the United States to comply with the DSB ruling and had accepted the extension of the implementation period. He said that the European Communities hoped that the United States would finally respect its compliance duty by 30 June 2005. Since the reasonable period of time for withdrawing the TRIPS-inconsistent measure was still running in this case, he said his statement would focus only on the first of these two disputes.

253. He said that a situation where a WTO Member did not comply with its TRIPS obligations even after an adverse panel ruling was a cause of concern for the European Communities and for the WTO membership as a whole. Such a situation might have a broader negative impact on the application of the TRIPS Agreement around the world. Therefore, in accordance with Article 68 of the TRIPS Agreement, the European Communities considered that the TRIPS Council should at this stage monitor more closely the United States' compliance with its copyright obligations as laid down in TRIPS.

254. The European Communities believed that it was in the best interest of the WTO Membership, including the United States, to ensure that appropriate information was available to the TRIPS Council about the steps that the United States was taking to amend its copyright legislation, in order to dispel any doubts about the United States' commitment to respect intellectual property rights. Such a constructive approach should induce other Members to take similar steps in similar situations. He said that his delegation was confident that the United States would have no problem in answering some specific questions, as a proof of its strong interest in the respect for the WTO rules on intellectual property. By providing full information about the specific steps that it had taken to comply with TRIPS internally, the United States would be able to prove that it was willing to apply at home what it requested from other Members.

255. He requested the United States to provide responses to the following three questions. First, whether there were any specific legislative initiatives in the United States to bring the Copyright Act into compliance with the TRIPS Agreement; in other words, whether, during the past four years, the US Congress had discussed any piece of legislation amending Section 110(5) of the US Copyright Act. Secondly, what specific steps the US Administration was taking to ensure that the United States would bring its Copyright Act into conformity with the TRIPS Agreement and whether there had been any written communication to Congress that the United States could share with the Council. Thirdly, when did the United States expect to finalize its work to comply with the WTO ruling that had been adopted in July 2000.

256. The representative of the United States said that, since he had not received advance notice of these questions, he would relate them to his capital and respond in the course of coordination with the European Communities. He said that the US administration had been consulting with the US Congress on this matter and would continue to work with Congress and to confer with the European Communities in order to reach a mutually satisfactory solution on this matter. He said that these points had also been made by his delegation in the DSB, which his delegation viewed as a more appropriate forum for the discussion of disputes, including compliance issues related to those disputes.

257. In response, the European Communities recalled that Article 68 of the TRIPS Agreement stated that the TRIPS Council should monitor the operation of this Agreement and, in particular, Members' compliance with their obligations thereunder. While the DSB was the right forum to discuss specific issues related to disputes, his delegation believed that the TRIPS Council had an interest in examining special situations of non-compliance with TRIPS obligations. The matters raised in the present meeting went beyond the specifics of a particular dispute and posed an important systemic issue in view of the fact that more than four years had lapsed since the adoption of the panel report. The TRIPS Council was, therefore, entitled to discuss the consequences of such a situation for the overall operation of the TRIPS Agreement.

258. The Council took note of the statements made.

O. OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

259. The Chairman said that the list of the 16 pending requests for observer status in the TRIPS Council by other intergovernmental organizations was contained in document IP/C/W/52/Rev.10. He recalled that the Council had discussed these pending requests at its previous meetings, but had not been able to reach consensus on any of them.

P. OTHER BUSINESS

260. The representative of the European Communities recalled that the TRIPS Agreement had entered into force ten years previously and that much had been done during this period to comply with its provisions, in particular those relating to enforcement, ensuring a balance between creating incentives for innovation through private rights and serving society's interest in the dissemination of knowledge through the limitation of these rights. However, during this period, counterfeiting and piracy had been increasing worldwide and had become a threat to the economy as a whole, and potentially dangerous counterfeit and pirated goods such as pharmaceuticals, foodstuff and drinks, car and aeroplane spare parts, electrical devices and industrial machinery were threatening consumers' or users' health and safety.

261. He said that effective enforcement of IPRs was clearly in the interest of all WTO Members, in particular developing countries which had an interest in attracting foreign investment, developing R&D activities, encouraging technology transfer and, above all, protecting their consumers who were often particularly exposed to sales of dangerous products, such as counterfeit medicines. Given the apparent contradiction between the introduction of the first comprehensive, multilateral set of IP enforcement rules and the increase in the levels of counterfeiting and piracy, his delegation wished to initiate a debate on this issue in the TRIPS Council pursuant to Article 68 of the TRIPS Agreement. He said that his delegation intended to submit a communication on this issue to the TRIPS Council at its next session in June. In order to organize the discussion in a structured and focused way, he suggested that a specific item on enforcement be added permanently to the agenda of the TRIPS Council.

262. The representative of Brazil said that, since Members were confronted with this proposal from the European Communities for the first time and without any advance notice, it was difficult for them to take a position on it at the present time. He said that he was looking forward to receiving the document foreshadowed by the European Communities. However, in the absence of more information and clarity on the nature, extent and objectives of the proposed exercise, he believed it to be entirely unreasonable to expect Members to agree to having a new item added to the agenda of the Council's next meeting. Therefore, he suggested that the Council should not agree to include the new item proposed by the European Communities on its agenda. The European Communities could raise the issue again under "Other Business" at the Council's next meeting and introduce its submission at that time. In the meantime, other Members could obtain proper instructions from their capitals in order to be able to respond to the proposal.

263. The representative of Argentina said that it was not clear to her what should be the scope of any debate ensuing under the proposal and that she preferred to wait for additional information in the document foreshadowed by the European Communities. In order to request instructions from her capital, she would need to know more details concerning the scope of and objectives pursued by that proposal.

264. The representative of India said that he would need instructions from his capital before being able to agree to the inscription of this new item on the Council's agenda, in particular as it was suggested as being a permanent item on that agenda. He hoped to receive the proposal well in advance of the Council's next meeting in order to be able to obtain instructions from his capital in time.

265. The representative of the Philippines said that it was of course the prerogative of any Member to seek the inclusion of any item on the agenda of a subsequent meeting, but it was equally the right of other Members not to agree to that agenda item, particularly if it was seen as falling outside the ambit of the jurisdiction of the TRIPS Council in this particular case. As a matter of procedure, since the matter had been raised under "Other Business", his delegation believed that the Council should not take any decision insofar as having the item inscribed permanently on the agenda of all TRIPS Council meetings, as this was not an appropriate decision to be taken under the heading of "Other Business". While acknowledging the information that the European Communities was offering regarding their intentions in respect of the Council's next meeting, he was not in a position to agree to the inscription of this item as a permanent agenda item in the Council's future meetings.

266. The representative of Switzerland said that Article 68 prescribed that the Council should monitor the operation of the Agreement, of which Part III on "Enforcement of Intellectual Property Rights" formed a part. Furthermore, Article 68 provided that Members be afforded the opportunity of consulting on matters relating to trade-related aspects of intellectual property rights. This would be the first time that a delegation was told to table a paper under "Other Business" with regard to a subject which clearly fell under the TRIPS Agreement. He noted that the agenda contained a number of items that his delegation disliked, but that did not mean that he would even consider demanding their deletion. He supported the EC proposal to include the item on the agenda of at least the Council's next meeting, so that the proposal could be tabled and correctly discussed under a clear-cut agenda item. To his knowledge, an item remained on the agenda for as long as it was being discussed by Members.

267. The representative of Cuba agreed with the statements made by Brazil, Argentina, India and the Philippines, and said that, in order to approve the inclusion of the aforementioned item on the agenda, she would need more information and instructions from her capital.

268. The representative of Japan welcomed the EC initiative as his Government was interested and engaged in the issues of enforcement and counterfeiting in the area of intellectual property. He had no difficulty in adding enforcement as a new agenda item and was looking forward to receiving the EC submission and starting a new discussion at the Council's next meeting.

269. The Chairman referred to Rules 3, 4 and 6 of the Rules of Procedure for Meetings of the General Council, and said that any item requested by any Member would appear on the agenda proposed for the subsequent meeting. Beyond that, he said that it had never been a tradition, neither in the years of the GATT nor of the WTO, to bar any item from discussion unless it was found to be outside the terms of reference of the body concerned.

270. The representative of India said that he had wanted to stress that the agenda item should be phrased in the form of a proposal and that no Member could have any objection to an agenda item in the style of "EC's Proposal on Enforcement". Furthermore, he said that he did not see any language in the General Council Rules supporting a decision to inscribe an item as a *permanent* item on the agenda. It was for these two reasons that he had suggested circulating the proposed submission well in advance to enable delegations to receive proper instructions from their capitals.

271. The representative of Malaysia said that, in view of the Rules of Procedure, the Council would be obliged to discuss a subject brought to it by a Member. In the context of enforcement, however, her delegation wanted to highlight Article 7 of the TRIPS Agreement, according to which the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. She expressed her delegation's hope that the subject of enforcement received a balanced treatment, as in any discussion in the TRIPS Council.

272. The Council took note of the statements made.

Q. ELECTION OF CHAIRPERSON

273. The Chairman said that, at its meeting of 15 February, the General Council had noted the consensus on the slate of the names of chairpersons for WTO bodies. On the basis of the understanding reached, he proposed that the Council for TRIPS elect H.E. Ambassador Choi Hyuck of Korea as its Chairman for the coming year by acclamation.

274. The Council so agreed.