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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

Held in the Centre William Rappard
on 16 June 2004

Chairman: Mr. Joshua C.K. Law (Hong Kong, China)

The present document contains the record of the discussion which took place during the TRIPS Council meeting held on 16 June 2004.

Subjects discussed — Page nos.

A. NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

1. The Chairman drew attention to the latest Secretariat note reflecting the status of the notifications of laws and regulations under Article 63.2 received from Members whose transitional periods under Article 65.2 or 65.3 had expired on 1 January 2000 or who had acceded to the WTO after that date (JOB(04)/68). The note showed from which of the Members in question notifications had been received by 3 June 2004. Since the Council's meeting in March 2004, Swaziland had notified its TRIPS implementing legislation. Among the 81 Members in question, there remained three who had not yet submitted any notification concerning their implementing legislation, namely Papua New Guinea; Saint Kitts and Nevis; and Saint Vincent and the Grenadines. He recalled that in the previous year, as requested by the Council at its meeting in February 2003, his predecessor had written to the Members that had not been represented at that meeting and which had unfilled notification obligations under Article 63.2. Since then, the Secretariat has had informal contacts with the three delegations that had not yet submitted any notification. He suggested that the Chair once again write to these three Members concerning the notification of their TRIPS implementing legislation.

2. Informing the Council about the supplements and updates to earlier notifications of laws and regulations that had been received since the March meeting, the Chairman said that the Czech Republic had notified a new Trademark Law and an Act on Courts and Judges; El Salvador had notified its "Law on Marks and Other Distinctive Signs"; Georgia had notified a list of geographical indications for wine, alcoholic beverages and mineral water; Germany had notified a "Law to Strengthen the Contractual Position of Authors and Performing Artists" and provisions of certain other laws in the area of enforcement; Hong Kong, China had notified recent amendments to its laws and regulations in the area of patents, designs and trademarks together with explanatory notes; Japan had notified an updated text of its "Customs Tariff Law"; Mexico had notified certain amendments to its industrial property laws and regulations; Panama had notified amendments relating to its criminal and judicial codes; Saint Lucia had notified legislation enacted or amended since the review of its legislation in 2001; and Tunisia had notified that it had ratified the Budapest Treaty. These notifications were being circulated in the IP/N/1/- series of documents. Furthermore, Armenia had provided its responses to the Checklist of Issues on Enforcement (IP/N/6/ARM/1).

3. The Chairman urged those Members whose initial notification remained incomplete to submit the outstanding material without delay. He also reminded Members of their obligation to notify any subsequent amendments of their laws and regulations without delay after their entry into force.

4. As regards notifications of contact points under Article 69, he said that, since the March meeting, notifications of new contact points had been received from Latvia and Swaziland. Furthermore, an updated notification of a contact point had been received from Angola. These notifications had been circulated in document IP/N/3/Add.7. There were now 120 Members who had notified contact points under Article 69.

5. The Council took note of the information provided and agreed to proceed as suggested by the Chair.

B. REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

(i) Follow-up to reviews already undertaken

6. The Chairman said that the Secretariat had updated its informal note that listed all the outstanding material required to complete the reviews that the Council had already undertaken (JOB(04)/67). The table attached to the note listed the 15 Members whose reviews had been initiated at the Council's meetings 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 7 June 2004.

7. He recalled that, at its last meeting, the Council had initiated the review of national implementing legislation of the Former Yugoslav Republic of Macedonia. Since that meeting, Switzerland had posed one follow-up question to the Former Yugoslav Republic of Macedonia (IP/C/W/419/Add.1).

8. The Chairman turned to the remaining 14 Members, namely Congo; Cuba; Egypt; Fiji; Grenada; Mauritius; Nigeria; Pakistan; Qatar; Saint Kitts and Nevis; Saint Vincent and the Grenadines; Suriname; Swaziland; and Zimbabwe.

9. The representative of Cuba said that she had nothing new to add to what her delegation had said in the last Council meeting with regard to Cuba's pending legislation. Her delegation intended to notify the laws, currently pending before the Council of the State, as soon as they had been adopted.

10. The representative of Egypt regretted that her delegation had not yet been able to submit responses to the outstanding questions and hoped to be able to do so in the near future.

11. The representative of Nigeria said that his delegation would provide responses to the outstanding questions before the next Council meeting.

12. The representative of Pakistan said that his capital had assured him that a response to the one outstanding question would be submitted before the next Council meeting.

13. The Chairman said that the Secretariat note also listed seven 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 this connection, certain questions had been raised with regard to the implementing legislation of these countries. Since the circulation of the note, China and Malaysia had provided responses to the follow-up questions that Japan had posed to them in relation to the responses that they had provided in the context of their regular reviews (documents IP/Q/CHN/1/Add.2 and IP/Q/MYS/1/Add.1, respectively).

14. The representative of Argentina said that responses to the pending questions would be communicated as soon as her delegation had received them from her capital.

15. The representative of Japan said that he appreciated the efforts made by China to reply to the questions posed by Japan. His delegation was examining these responses, and wished to reserve its right to put additional and follow-up questions to China, if necessary.

16. The Chairman noted that, since its last meeting, the Council had made very little progress in receiving the remaining outstanding material and thus completing the follow-up to the last pending reviews. He once again urged the delegations concerned to provide the outstanding material, so as to allow the Council to complete the follow-up to these reviews. He suggested that the Council request the Secretariat to update its note on pending reviews before the next meeting.

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

(ii) Review of legislation of Armenia

18. The Chairman recalled that, at its meeting in June 2003, the Council had agreed to review the legislation of Armenia, a newly acceded Member, at its meeting in March 2004. However, at that meeting, the Council, upon a request from the Government of Armenia, had decided to postpone the review to the present meeting. Armenia's notification of its TRIPS laws and regulations had been circulated in document IP/N/1/ARM/1, and the texts of the notified laws in the relevant law series of documents. Its responses to the Checklist of Issues on Enforcement had been circulated in IP/N/6/ARM/1. Armenia had received questions from Switzerland (IP/C/W/419). Its responses to these questions had been circulated in document IP/C/W/422.

19. In accordance with the standard procedures, the delegation of Armenia provided a brief introductory overview of the structure of its legislation in the areas covered by the TRIPS Agreement and of the changes that it had had to bring about in order to make the legislation compatible with the Agreement. The record of the introductory statement as well as the questions put to it and the responses given (including responses to any follow-up questions posed after the meeting) would be circulated in a document with the following symbols: IP/Q/ARM/1, IP/Q2/ARM/1, IP/Q3/ARM/1 and IP/Q4/ARM/1.

20. The representative of Switzerland commended Armenia for its efforts to bring its legislation into conformity with the TRIPS Agreement and other international agreements. He thanked Armenia for its responses to the questions posed by Switzerland. The responses to these questions contained the information his delegation had been seeking. He indicated that he would submit two follow-up questions to Armenia.

21. The Chairman requested that written copies of these follow-up questions be provided to the delegation of Armenia and the Secretariat. In accordance with the standard procedures, responses to them should be provided within eight weeks of the meeting. He suggested that the Council take note of the statements made and revert to the matter at its next meeting.

22. The Council so agreed.

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

23. The Chairman suggested that, since the practice in the Council's past meetings had been that delegates address these three agenda items together, the Council again take them up at the same time. He informed the Council that it had received a communication from Switzerland (IP/C/W/423), which contained additional comments by it on its proposals submitted to WIPO regarding the declaration of the source of genetic resources and traditional knowledge in patent applications.

24. Reporting on the consultations he had held on these three agenda items, he recalled that, at its meeting in March 2004, the Council had had extensive discussion on how future work on these three agenda items should be organized. At that meeting, the Chair had concluded that it might be necessary for his successor to hold consultations before the present meeting on this matter. Accordingly, he had held a series of consultations on this subject. These consultations had confirmed that there was a common view that it would be useful to find a way of having a more structured and

focused discussion in the TRIPS Council on these matters. A number of options for how this could be done had been put forward and discussed. He had detected some signs of flexibility and a broad willingness to engage in a process of identifying areas of convergence in regard to the provisions of Article 27.3(b), as had been suggested by the African Group. However, he regretted that, despite the efforts made by all parties, the consultations had not developed to a point where he would have been able to put a set of suggestions to the Council at this meeting.

25. The representative of Switzerland said that document IP/C/W/423 contained additional comments on the Swiss proposals to amend the Regulations of the Patent Cooperation Treaty (PCT), which had also been submitted to the sixth session of WIPO's Working Group on Reform of the PCT in May 2004. He recalled that the proposals would explicitly enable national patent legislation to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications, if their inventions were based on such resources or knowledge. The additional comments on the proposals concerned the use of terms, the concept of the source of genetic resources and traditional knowledge, the scope of the obligation to declare the source in patent applications, and possible legal sanctions for the failure to disclose or the wrongful disclosure of the source. By submitting the additional comments to the TRIPS Council, Switzerland aimed at informing the TRIPS Council of its efforts in the WIPO's Working Group on Reform of the PCT. He noted that the latest communication contained in document IP/C/W/423 complemented the two previous communications contained in documents IP/C/W/284 and IP/C/W/400/Rev.1.

26. With regard to the disclosure requirements under patent law, he said that paragraph 8 of Decision VII/19, adopted by the seventh meeting of the Conference of the Parties of the CBD in February 2004, invited WIPO to address issues regarding the interrelation between access to genetic resources and disclosure requirements in intellectual property rights applications. It was his delegation's view that WIPO should make significant progress on these issues and report the result of its work to the CBD in time. By submitting the additional comments on its proposals to the sixth session of the Working Group on Reform of the PCT, Switzerland intended to actively contribute to the work of WIPO in this regard. He said that the work of the TRIPS Council in the context of paragraph 19 of the Doha Ministerial Declaration should benefit and draw upon the relevant work being carried out by WIPO. This would help avoid duplication of efforts and prevent conflicting outcomes.

27. The representative of India welcomed the Chair's efforts in undertaking the informal consultations to structure the discussion on the basis of the checklist of issues identified by a group of developing countries to pursue their proposal on the disclosure of the source of genetic material and associated traditional knowledge and evidence of benefit-sharing. He said that this group of countries remained committed to pursue their proposal. They were encouraged by the widespread support received for the checklist, although consensus could not be reached on structuring the Council's work on the basis of the checklist. He reiterated his delegation's openness to incorporating other related issues in the checklist or exploring different ways which could help the Council focus its discussion in a result-oriented manner. Regarding the new submission by Switzerland, he said that it would help the Council address the concerns relating to the procedural issues involved in patent applications and the disclosure of the source of origin of biological materials.

28. The representative of the European Communities said that further discussions on the three agenda items should be guided by three principles: first, WTO Members should be faithful to the mandate under paragraph 19 of the Doha Ministerial Declaration; second, discussions should be conducted in a result-oriented manner to ensure that the implementation of the TRIPS Agreement and the CBD were mutually supportive, for which it was important that WTO Members, especially the *demandeurs* should clarify what result they wished to obtain; third, Members must focus discussions on a limited number of issues instead of continuing to have philosophical discussion on all the issues related to intellectual property and the CBD. He said that the issues of the disclosure of origin, farmers' exceptions and the protection of plant varieties were good candidates for such a focused

discussion. With regard to traditional knowledge and folklore, he said that Members could deal with certain disclosure issues related to traditional knowledge and folklore, but that it was difficult to start discussions on setting up an international regime for the protection of traditional knowledge. Since Members seemed to have reached an agreement to have a focused discussion, he urged Members to start identifying the issues they should focus on. Referring to the Swiss proposals which had been submitted to WIPO's Working Group on Reform of the PCT, he said that his delegation would come back to them at the Working Group's next meeting in November 2004.

29. He then said that he would make preliminary comments on the checklist of issues contained in document IP/C/W/420, without prejudging the outcome and without prejudice to the EC's positions in possible formal negotiating processes in the WTO or elsewhere. Regarding how an obligation for the disclosure of country and source of origin of the biological resource and associated traditional knowledge used in the invention would help in better examination of patents and in preventing cases of bad patents and what the meaning of disclosure of source and country of origin of the biological resource and of the traditional knowledge used in the invention was, he said that it was the view of his delegation that "disclosure of source or origin" referred to a requirement that a patent applicant should submit certain information to the patent office as regards the source and/or geographical origin of the genetic resource or traditional knowledge used in his biotechnological invention. This requirement could be calibrated in various ways according to the scope of the requirement, the type of information required and the legal consequence of non-respect of the requirement. He said that such a requirement should be sufficiently flexible to take account of the fact that the patent applicant might not reasonably know the geographical origin of the genetic resources used in the invention. For this reason, his delegation preferred to use the term "disclosure of source of genetic resources". He said that, in principle, all applicants should know the source of genetic resources or traditional knowledge. However, in certain circumstances it might be impossible or unreasonably burdensome for the applicant to investigate the entire chain backwards to the origin. An applicant should only be requested in good faith to reveal the best information available or known to him.

30. Regarding the advantage of the disclosure requirement, he said that this requirement, provided it was properly calibrated, would contribute to mutual supportiveness between intellectual property systems and access and benefit-sharing regimes for several reasons. First, the disclosure requirement would help the country who provided access to genetic resources to monitor and keep track of compliance with access and benefit-sharing rules, as well as with contractual arrangements between providers and users of genetic resources. Source countries would be informed of the patent application which incorporated genetic resources or traditional knowledge through foreign patent offices. This would enable them to check whether patent applicants respected national rules and contracts on access and benefit-sharing and to detect commercial benefits from the use of genetic resources. Second, the disclosure requirement would increase confidence among bio-collectors and biodiversity rich countries and indigenous communities. These countries or communities would generate less complex or burdensome but more effective national access and benefit-sharing regimes, thus creating a win-win situation for both providers and accessors. Third, the disclosure requirement would help to prevent inappropriate patenting of genetic resources or traditional knowledge because patent offices could establish more accurate prior art through more focused search. Lastly, the disclosure requirement would act as a strong incentive for patent applicants to comply with domestic rules on access and benefit-sharing, if they existed, and/or contractual arrangements. In sum, he said that the disclosure requirement would act as a supportive measure to biodiversity law at the national level to ensure transparency and to enable source states to check whether their national rules had been respected. It would also contribute to the effective implementation of the CBD. Furthermore, he said that an essential complementary measure to make the disclosure requirement effective would be the introduction of a simple notification procedure in patent offices. When a patent office received information on the source of genetic resources or traditional knowledge, it could notify this information to the clearing-house mechanism under the CBD. The information would therefore be available to all CBD parties as well as to the public. The introduction of such a procedure should not lead to an unnecessary administrative burden for the patent office.

31. As regards what the legal effect of wrongful disclosure or non-disclosure would be, he said that the effect could lie both within and outside patent systems, such as the one suggested by the Swiss proposal. He said that a requirement would be effective only if non-respect of it was sanctioned. However, at this stage, it was the European Communities' view that such sanction should lie outside patent law or should be self-standing, such as civil law or administrative sanctions. He informed the Council that this issue was at present under further internal discussion as a consequence of the European Commission's Communication of December 2003 on the implementation of the Bonn guidelines.

32. As regards the question of on whom the burden of proof should lie, he said that applicants should be requested to provide all reasonably available evidence of the source and/or geographical origin of genetic resources and traditional knowledge. It was up to those who might wish to contest such disclosure in an administrative procedure or before a court to provide contrary proof according to usual rules.

33. Regarding the inclusion of the proposed obligation of disclosure of source and country of origin and associated traditional knowledge in the TRIPS Agreement, he said that his delegation did not exclude the possibility of inserting such an obligation in the TRIPS Agreement, provided it was properly calibrated. However, he thought that, at this stage, it might be premature to start discussions on how and where such a requirement should be set in the TRIPS Agreement. The answer to this question would depend on what substance could be agreed on. There were many options, such as inserting a new article or a new obligation to the existing articles of the TRIPS Agreement.

34. Turning to the disclosure of the evidence of prior informed consent and benefit-sharing under relevant national regimes, he said that, at this stage, his delegation saw serious problems with the introduction of a system whereby patent applicants were required to provide such evidence. First, it was difficult for patent offices to judge whether foreign country legislation on access and benefit-sharing had been complied with. The main function of patent offices was to ensure that patentability requirements were met, which was a difficult task, especially in the field of biotechnology. Requesting patent offices to verify whether patent applicants had respected all legal rules related to the material used in their inventions would seriously overburden patent offices and create legal interpretation problems. He said that the patent office was not required to check whether the applicant had paid VAT on the lab material used for the invention or whether he had respected the legal requirement for the stockpiling of the chemicals used in the research activity although this requirement was important to *ordre public*. Therefore, he said that although it would be reasonable to entrust patent offices with the task of collecting information on the source of genetic resources or traditional knowledge and transmitting it to a clearing-house mechanism, checking compliance with foreign access and benefit-sharing rules would be one step too far at this stage. Second, he said that many countries did not yet have national legislation on access and benefit-sharing and were not in the position to deliver the certificate of origin, which made the requirement of the disclosure of the evidence of access and benefit-sharing more difficult, if not impossible, to manage.

35. With respect to how furnishing the evidence of prior informed consent would facilitate achieving the objectives of the CBD of ensuring prior informed consent and a harmonious relationship between the CBD and the TRIPS Agreement and whether contractual arrangements for ensuring prior informed consent and benefit-sharing could suffice to achieve the objectives of the CBD in this regard, he said that effective implementation of the CBD resided in a combination of legislative, regulatory and contractual approaches.

36. Regarding how the evidence of prior informed consent through approval of authorities under the relevant national regime should be provided for, he said that a uniform approach in the form of uniform certificates as proposed by several countries and non-state actors could be a solution. He said that proposals to this effect had been made *inter alia* by Switzerland as well as by the like-minded mega-diverse countries in the Cancun Declaration of 18 February 2002. The seventh meeting of the

Conference of the Parities of the CBD had adopted terms of reference for the negotiation of an international regime on access and benefit-sharing. The issue of a certificate of origin was part of the terms of reference. The European Communities agreed that this issue should be dealt with as a matter of priority.

37. Regarding what the obligation should be if there was no national regime in the country of origin, he said that since many countries did not have such a national regime or had a region that was not yet fully operational or effective, it was premature to consider the requirement of disclosure of evidence of access and benefit-sharing.

38. The representative of Kenya said that some delegations had indicated in the informal consultations that they would like to come back at a later stage to the suggestions on how to organize the further work made by Chair in the course of these consultations. Therefore, he hoped that the Chair's suggestions would remain on the table so that they could come back to them after further consultations.

39. The representative of Brazil fully supported the intervention made by India on behalf of the co-sponsors of document IP/C/W/420. Referring to the new Swiss submission, he said that it was constructive and should be complementary to the discussion in the TRIPS Council. He thanked the European Communities for their constructive statement, and said that all the matters in the checklist should be looked at carefully by the Council. He hoped that his delegation would be in a position to reply to the points raised by the European Communities in the near future. He also said that the European Communities' substantive and constructive intervention and other favourable reactions to the checklist of issues showed that there was plenty of space to move forward on this issue in the Council.

40. The representative of Malaysia said that her delegation understood the need for a focused and structured discussion on the issues under paragraph 19 of the Doha Ministerial Declaration. She indicated that the checklist of issues identified in document IP/C/W/420 could form a basis for the Council's further discussion. She also noted that there was flexibility in adding other elements to this discussion but it should be without prejudice to the positions of delegations on these issues. She said that further discussions and clarifications on certain terms, such as "country of origin" and "source of origin" would be useful. As regards disclosure of the evidence of benefit-sharing, she sought clarification on whether it would be applied to the provider of genetic resources or to the provenance of genetic resources.

41. Further she raised preliminary questions on the Swiss submission: first, under the Swiss proposals, patent applicants were required to declare the source of genetic resources and traditional knowledge, which included all entities competent to grant access and participating in the benefit-sharing. As to the scope of the obligation to declare the source, the Swiss proposals suggested that the invention must make immediate use of genetic resources, that is depending on the specific properties of these resources. She sought clarification of the term "immediate", whether it denoted a time dimension other than making use of a specific property of the genetic resource. Second, as regards the definition of the source, Switzerland viewed the source as entities involved in granting access to genetic resources and traditional knowledge and the sharing of benefits arising from their utilisation. She questioned whether the declaration of source should be made by any one of these entities or as many as could be identified and what the consequence of inadvertently leaving some out in patent applications would be. Third, referring to paragraph 22 of document IP/C/W/423 which said that the source could include databases and other publications, she questioned whether these databases and publications should be involved in access and benefit-sharing or be just treated as a source of origin.

42. Reacting to Brazil's intervention, the representative of the European Communities said that it was crucial that the *demandeur* countries could put forward their views on this issue as soon as possible. Those which had experiences on implementing relevant requirements could share their experiences with others and this was essential for Members to have further discussions on this issue.

43. Referring to the point made by the delegation of Kenya, the representative of Canada said that it would be helpful to have a more focused and structured work plan. Therefore, he hoped that the Chair's proposal presented in the informal consultation on 10 June 2004 was still on the table. He also noted that the work plan would be without prejudice to Members' positions, that any new issue could be raised, and that the proposals that had already been tabled would still remain on the table.

44. The representative of Australia said that her delegation supported the efforts made to structure discussions on these three agenda items. She said that the suggestions that the Chair had made in the course of informal consultations had taken Members in a helpful direction and would allow Members to work in a manner that was consistent with the Doha Declaration. She noted that the proposal would be without prejudice to Members' positions and other proposals that had already been or might be on the table. She further indicated that Members needed to have a proper examination of, as indicated by paragraph 19 of the Doha Declaration, where they were now on some of these issues. She agreed with the European Communities that Members needed a much firmer basis for further discussions, particularly as regards national experience.

45. The representative of New Zealand said that her delegation supported the efforts made to facilitate the progress under paragraph 19 of the Doha Declaration. She said that the three issues were important to New Zealand and deserved the TRIPS Council's consideration. She agreed that the Council needed to have a more structured discussion. It was a sensible way forward for Members to separate the issues and then focus on the issues which they could reasonably expect to make progress sooner or later. She supported the comments made by Canada, Kenya and Australia, hoping that Members could return to the Chair's suggestions that had been put forward in the informal consultation.

46. The representative of the United States said that his delegation, like a significant number of other WTO Members, saw no conflict between the TRIPS Agreement and the CBD and believed that they might be implemented in a mutually supportive manner. Nonetheless, his delegation could agree that the TRIPS Council should have a more organized work plan to support continued discussions on the relationship between the TRIPS Agreement and the CBD as well as related traditional knowledge. However, he noted that the elements of the work plan should be broad enough to ensure all Members' views to be properly considered and expressed. His delegation continued to believe that the checklist as proposed in document IP/C/W/420 was not the best approach for the Council at this time.

47. He noted that, in the Council's previous discussions aimed at fulfilling the Doha mandate, Members had appeared to generally share certain broad policy objectives. His delegation believed that these commonly agreed objectives could better structure the TRIPS Council's work without prejudice to Members' views on appropriate mechanisms, means or forums to pursue these objectives. These objectives might include achieving an appropriate access to traditional knowledge and genetic resources as well as equitable benefit-sharing, preventing misappropriation of traditional knowledge and genetic resources as well as preventing improperly granted patents. Within the context of these topics and the scope of the Doha mandate, he believed that Members could identify their concerns, share their national experiences, and develop some options and proposals, which would provide more specific focus than the previous TRIPS Council's work, and therefore help to facilitate the Council's discussions.

48. As regards the substantive comments made by the European Communities and Switzerland, he reiterated that his delegation continued to oppose the efforts to try to enforce the CBD through the patent system. Instead, his delegation continued to believe that national systems, independent from

patent systems should be adopted to regulate the issues of prior informed consent, benefit-sharing and misappropriation of resources. In conclusion, he reiterated that his delegation remained open to working with others on creating a better structure for discussions in this regard, but the work plan must be broad enough to ensure that all Members' views could be properly considered and expressed during the debate.

49. The representative of Norway recalled that, at the Council's last meeting, his delegation had indicated that the checklist in document IP/C/W/420 could be a basis for the Council's deliberations. He said that the list of issues should be sufficiently comprehensive so as to reflect all the discussions Members had had in the past few years and should not prejudice Members' views on those issues.

50. The representative of Japan said that his delegation agreed that the Council should focus its discussions on a limited number of items. However, he thought that the checklist in document IP/C/W/420 did not seem to be constructive. Therefore, his delegation supported to continue informal consultations on these matters.

51. The representative of Chinese Taipei said that his delegation would make comments on Switzerland's new submission in due course. Since many issues needed to be clarified in different dimensions, it would be helpful to have a focused discussion. Therefore, he supported the Chair's suggestion to focus the discussion on a limited number of items, such as the disclosure requirements.

52. The representative of Switzerland said that his delegation would respond to the questions posed by the delegation of Malaysia at the next TRIPS Council meeting. With regard to the procedure, he echoed some delegations' support to the Chair's suggestions on the future work of the Council.

53. The Chairman suggested that the Council revert to the questions raised concerning the Swiss paper at its next meeting. As regards how to organize future work on these three items, he recalled that many favourable comments had been made on the ideas he had put forward at the Council's informal consultation on 10 June 2004. He had detected willingness to find a way forward which would enable the Council to move its discussions to a more substantive stage. He said that the spirit of the suggestions he had made in the informal consultations was to find a way forward by looking at all the proposals submitted by delegations so far and to come up with a structure, which would avoid prejudicing the positions of delegations. He recalled that, in the course of the informal consultations, he had made it clear that all the papers that had been submitted would be fully taken into account in the Council's work under any such structure. He reaffirmed that agreement to work on the basis of any such structure should not be taken as in itself prejudicing the position of any delegation on any matter of substance. Responding to the questions raised by some Members, he said that all the proposals which were on the table, including the suggestions he had made in the course of the informal consultations, would remain on the table. Any other proposal which might be put forward should also be taken into account. He suggested that the Chair continue consultations on how future work on these three agenda items should be organized. Finally, he encouraged Members to make constructive comments on the existing proposals and to try to find a way of having a focused and structured discussion in the TRIPS Council on these three items.

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

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

55. No statements were made under this agenda item. The Council agreed to revert to the matter at its next meeting.

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

56. The Chairman recalled that Article 24.2 provided that the Council should keep under review the application of the provisions of the geographical indications Section of the TRIPS Agreement, and that the first such review should take place within two years of the entry into force of the WTO Agreement. At its meeting in June 2003, the Council had invited those Members that had not provided information in response to the Checklist of Questions contained in documents IP/C/13 and Addendum 1 to do so. Since the Council's meeting in March 2004, further information in response to the Checklist had been received from Chinese Taipei. These responses had been circulated in Addendum 30 to document IP/C/W/117. To date, the Council had received responses to the Checklist from 46 Members.

57. The representative of Chinese Taipei said that her delegation's responses to the Checklist were intended to facilitate Members' understanding of the relevant systems in Chinese Taipei. Geographical indications were eligible for protection under the Trademark Act, the Tobacco and Alcohol Administration Law, and the Fair Trade Law. They were generally protected as certification marks under the Trademark Act on the basis of the "first come, first served" principle. If the use of geographical indications constituted unfair competition, the Fair Trade Law could provide protection. Mislabelling was regulated under the Tobacco and Alcohol Administration Act.

58. The Chairman recalled that, prior to the Council's meeting in March 2004, his predecessor had held consultations on how to carry forward this review. In the light of those consultations and the discussions at that meeting, he had concluded that there remained differences of view on how to carry forward the review. The Council had agreed to keep this matter on its agenda so that Members could revert to the issue of how to structure the review at a later stage.

59. The representative of Australia said that she agreed with the Chair's characterization of the situation as regards the review. She thanked Chinese Taipei for its responses to the Checklist of Questions, and encouraged other Members to make such contributions in order to build a basis for the Council's further consideration of this issue.

60. The representative of the European Communities said that his delegation would examine Chinese Taipei's responses and come back with further questions at the Council's next meeting. As regards how to carry forward the review, he encouraged the Chair to think about the possibility of tabling an option paper which would help delegations to move forward.

61. The representative of Kenya sought clarification from the European Communities as regards the registration of foreign geographical indications under the EC regulation. He said that information from the Kenyan producers indicated that the regulation might be unfriendly in relation to foreign applications.

62. Responding to the question posed by Kenya, the representative of the European Communities said that the EC regulation on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (Regulation No. 2081/92) applied to geographical indications relating to areas located inside as well as outside the European Communities. For this purpose, the Regulation laid down rules relating to the registration of geographical indications from outside the European Communities which closely paralleled the provisions applicable to geographical indications from inside the European Communities. The purpose of these specific rules, some of which had been recently introduced by Regulation No. 692/2003, was to facilitate the registration of non-EC geographical indications while at the same time ensuring that geographical indications from outside the European Communities corresponded to the definition of a geographical indication.

63. As to the conditions which must be fulfilled for registration to take place, he said that some WTO Members had considered, on the basis of Article 12(1) of Regulation No. 2081/92, that the registration of geographical indications from outside the European Communities was possible only under conditions of "reciprocity and equivalence". However, Article 12(1) of Regulation No. 2081/92 provided that it applied "without prejudice to international agreements", including the TRIPS Agreement. Since WTO Members were obliged to provide protection to geographical indications in accordance with the TRIPS Agreement, the reciprocity and equivalence conditions mentioned in Article 12(1) of Regulation No. 2081/92 did not apply to WTO Members. In other words, the EC GI register was open to geographical indications from other WTO Members, and the registration of such geographical indications may take place on the same substantive conditions which applied to the registration of geographical indications from EC member States.

64. The representative of Australia said that her delegation had serious concerns about the consistency of the above-mentioned EC Regulation with the TRIPS Agreement. The response by the European Communities was not clear-cut and did not give the answer her delegation was seeking. As regards the question of whether or not there should be an option paper, she said that, although she thought that such a paper was not necessary at this point, she preferred to leave the question in the Chair's hands.

65. The representative of the United States generally supported the remarks by the representative of Australia, particularly regarding a possible option paper. He said that the preparation of such a paper seemed premature at this time. However, his delegation was open to being further engaged in this matter, including possible Chair's further consultations with Members.

66. The Chairman said that, as regards the specific suggestion by the European Communities, this was a matter for the Chair to reflect upon and consider after further contacts with delegations.

67. The Council took note of the statements made.

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

68. The Chairman recalled that, at its meeting of 30 August 2003, the General Council had adopted the decision on "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (WT/L/540). Paragraph 11 of that Decision provided that the Decision, including the waivers granted in it, should terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions would take effect for that Member. Furthermore, it instructed the TRIPS Council to initiate, by the end of 2003, work on the preparation of such an amendment with a view to its adoption within six months, i.e. by June 2004, on the understanding that the amendment would be based, where appropriate, on the Decision, and on the further understanding that it would not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration.

69. He recalled that, at the Council's meeting in March 2004, his predecessor had reported on his consultations on the implementation of paragraph 11 of the Decision. In summarising his report, he had noted his consultations had revealed that there seemed to be significant differences among delegations in regard to the substantive content and the legal form that an amendment to replace the paragraph 6 Decision should have, although many delegations had emphasised that they remained ready to consider alternative solutions. He had concluded that further work was required.

70. The Chairman said that his own consultations prior to the present meeting had indicated that, in regard to issues of content and legal form, positions had not evolved. With regard to the issue of timing, he said that there was general acceptance among delegations that the Council would need more time in order to complete its work on the amendment. As regards such further work, he

mentioned four points on which his consultations had indicated that there was no disagreement. First, given that the Decision remained in force until the amendment came into force, providing more time would not mean that any gap in legal cover would be created. The second was that all Members continued to be committed to replacing the Decision of 30 August 2003, with an amendment to the TRIPS Agreement, as called for by paragraph 11 of that Decision. The third was that the time-frame specified in paragraph 11 was one which provided for flexibility, with the use of the words "with a view to its adoption within six months", and this left it open to the TRIPS Council to provide for more time for this work if necessary. The fourth point was that paragraph 8 of the Decision provided for the TRIPS Council to review its functioning annually, which meant that the first such review would take place later in the year.

71. While there was a range of views on the arrangements that should be made for the further work on this matter, the consultations had indicated a willingness to look positively at finding a way forward on the basis of a formulation where the Council would agree to continue its work on the preparation of the amendment 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.

72. The Chairman drew the attention of the Council to the addendum to the note by the Legal Affairs Division of the Secretariat on the legal significance of footnotes in WTO agreements, dated 12 May 2004, which had been prepared at the request of his predecessor. The note attempted to respond to some additional questions of a legal nature that had been raised by a number of Members when the first note had been discussed at the Council's informal meeting of 4 March 2004.

73. The representative of Nigeria said that, while the African Group was in favour of the Chairman's proposal concerning the conclusion of the work by the end of March 2005, it believed that the Council could conclude such work even before that date. Further, with regard to the note of the Legal Affairs Division, he said that the African Group would present written comments on it at a later stage.

74. The representative of Chinese Taipei said that he believed that the amendment should remain essentially technical and neutral in nature in order to translate into the text of the TRIPS Agreement exactly what the Council had decided, without any risk of alternative interpretations. He accepted the extended timeframe and hoped that the Council could successfully conclude the amendment during that period.

75. The representative of Tanzania said that the LDC Group would revert back to the Chairman on his proposal.

76. The representative of Lesotho associated himself with the statement that Tanzania had made as the coordinator of the LDC Group and said that, for his delegation, the lack of an amendment to the TRIPS Agreement meant that the nature of the Decision of 30 August 2003 remained temporary and that it remained difficult for Members with insufficient manufacturing capacity to attract investments in the pharmaceutical sector so as to improve their capacity to address their public health concerns.

77. The representative of Argentina said that she could accept the proposal the Chairman had formulated on extending the timeframe. She wanted, however, to refer in greater length to two issues which the Chairman had raised, namely the form and the content of the amendment and the Secretariat notes which had been circulated.

78. She said that, in its note of 1 March 2004, the Secretariat had stated that neither Article X of the WTO Agreement nor the Vienna Convention on the Law of Treaties referred to the question as to whether a footnote could be used to amend the substance of a treaty. The Secretariat had noted the existence of a considerable number of footnotes which it described as "substantive" in nature. In its

note of 12 May 2004, the Secretariat further considered that the precedents set by the panels and the Appellate Body of the WTO confirmed that footnotes had been used for substantive provisions in several WTO agreements and were interpreted in the same way as provisions in the main text of the agreements concerned. The Secretariat had concluded that there was no formal reason either in the law or the jurisprudence of the WTO that would preclude amending an agreement, including the TRIPS Agreement, through a footnote. Indicating that the Dispute Settlement Body had not differentiated the legal effects of footnotes from the main text of the Agreement, the Secretariat had concluded that it would not be contrary to the TRIPS Agreement to amend it through a footnote as long as the procedure of Article X of the WTO Agreement was respected.

79. She said that although the 12 May note of the Secretariat had indicated in paragraph 3 that it did not intend to analyse the appropriateness of each course of action, she believed that paragraph 29 did prejudge the appropriateness of the different courses of action by stating that "apart from a footnote", "other" possible legal forms had been mentioned, as if these were of secondary importance.

80. In her delegation's view, the main issue with regard to footnotes relates to the interpretation made in general in the context of treaties, in particular to the WTO agreements and more specifically to the TRIPS Agreement. She added that it was not customary under the law of treaties to amend a treaty through a footnote which was usually considered to be subordinate in nature to the main text and could not take precedence over it, but could merely be supplementary or clarificatory in nature. The legal form was of particular importance with respect to the amendment following the Decision of 30 August, since such an amendment would not be merely a clarification, but would modify the legal effects of Article 31 of the TRIPS Agreement. According to her delegation, an analysis of the footnotes in the WTO agreements referred to by the Secretariat as being "substantive" would show that most of them served the purpose of clarifications referring to the way in which the text of the treaty should be interpreted or supplemented. For example, the TRIPS Agreement contained 14 footnotes, none of which contradicted the main body of the text, although footnote 12 was the only one which could be considered to modify the effects of the Agreement, since it contained the sentence "shall not be required to". Even this footnote did not in fact create an exception to an obligation or contradict the main text – as would be the case if the Council introduced the Decision of 30 August into the TRIPS Agreement. Besides, the footnotes to the Agreement were introduced at the time of its negotiation and not as the result of later amendments. On the occasions when the provisions of GATT were amended, the amendments were set out in the form of protocols.

81. As to the jurisprudence cited by the Secretariat, she did not see any relevant material with regard to how to interpret a footnote when it was not supplementary or merely subordinate to the main text. In view of that, it needed to be determined whether a footnote was the appropriate legal form for creating an exception to Article 31 of the TRIPS Agreement. Article X of the WTO Agreement contained the procedure for amendment of WTO agreements and the Secretariat had clearly set out in its documents that this procedure must be followed in incorporating the Decision of 30 August through an amendment, irrespective of the legal form that was chosen for the amendment. A footnote would thus not simplify the amendment procedure to the Agreement since the Council would have to follow the procedure of Article X. What, then, were the advantages of adopting an amendment through a footnote? The proponents of this form of amendment were those who advocated incorporating not only the Decision, but also the Statement of the Chairman of the General Council (hereinafter referred to as "the Statement"). The only motivation Argentina saw for such proposal was that a footnote would facilitate the introduction of the Statement into the TRIPS Agreement, giving it the same legal status as the Decision.

82. She said that the Statement had clearly been drafted to enable all Members to join the consensus on the adoption of the Decision. In the view of her delegation, the Statement was a unilateral instrument without any binding effect and its legal value and status were distinct from that of the Decision adopted by the General Council. At no stage had the Chairman or the Members construed the Statement as being part of the Decision, but rather as an instrument which would

facilitate a consensual decision on the Decision. From the standpoint of Article 31 of the Vienna Convention on the Law of Treaties, one could analyse whether the Chairman's Statement could in fact be considered to be part of the "context" of the amendment. Her delegation believed that for the purposes of interpretation, the Statement did not reflect an "agreement" between the parties within the meaning of paragraphs 2(a) and 2(c) of Article 31 of the Convention. She said that the Secretariat had cited precedents to determine whether the Statement could be considered under Article 31.2(b) of the Convention (i.e. as "any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty"). She also said that the Secretariat had taken the view that a statement made by one party could be considered as part of the context of the treaty or as an instrument related to the treaty. In the case at hand, she said, the Chairman's Statement was not, however, an instrument which had emanated from a "party", i.e. a WTO Member.

83. The representative of Argentina said that it was equally clear that there was no consensus amongst Members with regard to the legal value of the Statement, and indeed, most Members had explicitly stated that the Statement lacked legal value to become part of the amendment. Her delegation believed that only the Decision of 30 August adopted by Members should be considered in the process to amend the TRIPS Agreement. The Secretariat had stated that the incorporation of the Statement would not be decisive in assessing the legal value of the Statement, but that the latter would depend on the actual text of the footnote. Her delegation disagreed with that argument, since there should be unanimity on the value of the Statement for it to have legal value in the light of Article 31 of the Vienna Convention.

84. In conclusion, the representative of Argentina said that, in view of the foregoing, her delegation believed that the most important value to be preserved was legal security. She said that the Chairman's Statement could not be part of the amendment as it was a unilateral statement which was not included in the agreement reached by Members, i.e. in the Decision of 30 August, and to introduce it would establish a bad precedent amounting to a disguised amendment to the provisions of the TRIPS Agreement through unilateral instruments, which were not generated by one of the contracting parties and which did not constitute an agreement between the parties. In her view, a footnote referring to a decision such as the one of 30 August 2003 could prove controversial. She further said that the amendment did not have as its objective the clarification of the text of Article 31 or to supplement it to avoid its misinterpretation, but rather an authorisation to Members to carry out activities which, according to Article 31, were not at present permitted. The amendment would be the subject of interpretation in the future and this task would not be facilitated by an amendment in the form of a footnote. Apart from the fact that there were no precedents on this form of amendment, her delegation did not consider such an approach to be appropriate from a systemic standpoint.

85. The representative of Israel said her delegation was committed to concluding the process related to the Decision on the TRIPS Agreement and Public Health and welcomed the work plan suggested by the Chairman. Since the text of the 30 August Decision contained all the necessary elements, an amendment to the TRIPS Agreement should not require any renegotiation. She reaffirmed Israel's position that the Chairman's Statement could not be included "as is" in any amendment.

86. The representative of the European Communities said that his delegation accepted, with regret, the proposal of the Chairman for extending the deadline for agreeing to an amendment because there was no other choice. He said that the European Communities had always favoured an amendment as the best way to guarantee legal security for those who needed it. His delegation did not understand how the Council had come to a situation where it could not agree that this should be a simple technical exercise of inserting what had been agreed upon in August 2003 into the TRIPS Agreement, but it seemed that some Members wanted to get, in this process, what they could not get in August 2003. If this was the case, there was no indication in the foreseeable future that the Council could come to any agreement on the substance which was different from what it had managed to agree

a few months earlier. He had the impression that some suggestions that had been made on the substance departed from what had been agreed, either by changing the balance between the Decision and the Statement or by trying to review some conditions that had been agreed to.

87. He said that meanwhile Members did have a waiver, which, while not being the best solution available, was a good solution and one on which Members could act. He said that no Member had notified its need for importing medicines under the system, but there might have been very good reasons for that. For instance, until Canada and Norway had adopted legislation allowing the use of the system for production for export, it had not been possible to find supplies under the system. Nevertheless, he said that this gave grounds to certain industrialised countries that had been sceptical on the issue of TRIPS and public health to question whether the real problem was patents. This was not the view of his delegation which had agreed to address the problem in the TRIPS Council and had finally agreed to a solution. He was interested in learning the reasons why no notification had been made, because that would help his delegation in responding to questions on this issue, as the Commission was to propose legislation to Parliament to implement the paragraph 6 agreement.

88. He said that the delegation of Argentina had raised valid and pertinent points, although he could not agree with all issues raised. He clarified that his delegation believed that the Statement had a different legal status from the Decision. This did not mean that the Statement had no legal value at all as it was part of the context of the Decision, referred to the Decision and had been read out in the meeting where the Decision had been adopted. The value of the Statement was that it did clarify some issues, making more explicit what was already in the Decision but it did not and could not change the content of the Decision. His delegation believed that there was no need to upgrade the legal value of the Statement and that it would be inappropriate to upset the balance between the Decision and the Statement or to downplay the importance of the Statement. He believed that the Statement was important for one WTO Member to adhere to the Decision, and the Council had to respect this. He said that the Statement was on the record of the General Council meeting that had adopted the 30 August Decision and it expressly related to the Decision. Since the amendment would be based on the Decision and in principle should be almost a copy of it, the Statement should and would automatically continue to apply to the new TRIPS provisions.

89. As regards the legal form, he said that his delegation was open to a footnote, so long as it would change the rights and obligations of Members along the lines that had been agreed on 30 August 2003. If a number of Members felt that a footnote was inappropriate, perhaps more for political reasons, his delegation would prefer one paragraph in the TRIPS Agreement, which would clearly set out the new exception, and an annex to the TRIPS Agreement, which would list all the additional conditions as they appeared in the Decision. His delegation could equally agree that the exception be part of a footnote, although he saw no reason why it should be in a footnote if usually rights and obligations were part of the text of an agreement.

90. He said that the Commission was working on the regulation to implement the paragraph 6 decision to allow producers in Europe to rely on a compulsory licence for export, but that might take time since the European Communities had very specific decision-making procedures to be respected. The Commission had almost finalised its draft and, if it could be agreed upon within the Commission by summer 2004, the Commission could submit a proposal to the European Parliament. His delegation hoped that the Commission could do it before it resigned by the end of October and, if this were not the case, then the next Commission would make it before December 2004 after which it would have to be approved by the European Parliament and the Council.

91. The representative of Kenya stated that he would have preferred to have had a permanent solution in place by the date of the meeting. He said that the Council was guided by paragraph 11 of the Decision, especially where it stated that the amendment would be based "where appropriate" on the Decision. He informed the Council that Kenya was in the process of notifying but had found out that it was not very easy to use this particular solution and that was why he wished to have a

permanent one in place so that his country could amend its domestic laws. He added that Kenya would notify its use of the system most probably before the end of the year. Finally, he reminded Members of the process that the Council went through on 28 and 29 August 2003, when there had been other statements that were also important to convince delegations to accept the Statement, especially the statement made after a consultation undertaken by the representative of South Africa.

92. The representative of Turkey expressed his delegation's unconditional acceptance of the Chairman's proposal concerning the extension of the timeframe. He said that his delegation agreed fully with Argentina's intervention, not for political or juridical reasons, but because his delegation believed that the modification of the Agreement by a footnote would be a fundamental error. He said this would be like modifying a constitution or a statute by a ministerial circular. With regard to the legal value of the Statement, his delegation shared the views of the European Communities. Finally, he said that these were only preliminary views and reserved the right to state his definitive position at a later meeting.

93. The representative of the Philippines said that his delegation was open to the Chairman's proposal, and believed that even if the Council did not reach an Agreement on the Chairman's formulation by 30 June, the Council's mandate continued. His delegation supported the statement made by Argentina. He agreed with the statement of Kenya that other statements made on the record at the time of the adoption of the Decision in the TRIPS Council and prior to the adoption of the Decision in the General Council were integral parts of the context of the adoption of the Decision. With regard to the Secretariat's note, he said that such a note had no legally binding value, and the positions stated therein had not been agreed upon by the membership and should not be accorded any legal probative value. He said that the footnote approach was not considered appropriate by his delegation to incorporate such an important amendment to the TRIPS Agreement.

94. The representative of Switzerland said that his delegation could agree with the Chairman's proposal to extend the deadline for the work of the Council on the amendment. Like Kenya, he wished that the Council had met the deadline and had fulfilled its mandate as was foreseen in paragraph 11 and looked forward to completing this as quickly as possible. He believed this to be a technical exercise and one should not attempt to change the substance of the agreement that had been confirmed in 30 August 2003.

95. He pointed out the helpfulness of the notes prepared by the Secretariat on the legal significance of footnotes and said that his delegation was surprised with the intervention of Argentina and its interpretation of the note. He understood that the note had confirmed that amendments of WTO agreements, such as the one to be made for implementing the paragraph 6 Decision, could take the legal form of footnotes. He added that the note had stated that the TRIPS Agreement already contained substantive footnotes providing for limited exceptions to provisions set out in the body of the text. This approach seemed to be perfectly appropriate for introducing the solution Members had found into the TRIPS Agreement and to do this in an efficient and expeditious manner since it would allow, by way of reference, to incorporate the 5-page long text of the paragraph 6 decision into the TRIPS Agreement in an easy manner, without upsetting the structure of the Agreement or prejudicing its readability or comprehensibility.

96. His delegation held the view that there had been a general agreement among Members on 30 August 2003 that the Statement had a crucial role to play in reaching the agreement and finding the solution. The Statement had been made by the General Council Chair with the collective understanding and the agreement of the membership and it was therefore also clearly distinct from other statements made on that day by individual delegations. Both parts of the solution should be reflected in an amendment, although there was consensus among the membership that the form of this amendment should not alter the legal status of the Decision and the Statement. Accordingly, appropriate wording in the amendment would have to be chosen in order to achieve this goal. He joined other delegations in thanking Canada and Norway for their presentations of the state of play of

the implementation of the Decision in their legislation. He informed the Council that Switzerland was currently revising its patent legislation in order to implement the Decision to provide for a compulsory licence for export purposes.

97. The representative of Japan said that the extension of the timeframe should be as short as possible because, if the Council sets a longer period, it might be possible to re-open the discussion on substantive points. He said that he could support the Chairman's suggestion of a 9-month extension through March 2005. As to the content, his delegation believed that a reference to both the Decision and the Statement was necessary in order to reflect the agreement correctly. As to the legal form, his delegation thought that the amendment of TRIPS should be one which reflected what Members had already agreed and that using the footnote approach seemed to be a simple way of doing this.

98. The representative of Korea supported the Chairman's proposal to extend the time to the end of March 2005. He reiterated his delegation 's view that the amendment of the TRIPS Agreement should be a technical exercise of transplanting the Decision into the TRIPS Agreement without opening the substance for renegotiation. He believed that this exercise could and should be completed in a short period of time and was disappointed that the Council had not been able to meet the original target date of 30 June 2004. He noted that the Decision had been the outcome of long and difficult negotiations and as such reflected a delicate balance of interests among Members. Korea was not convinced that the attempts to renegotiate the substance, which would certainly be another difficult exercise, would serve the interests of either the Members or of the Organization. In this context, the proposal of the Chairman to extend the target date by a relatively short period of time, i.e. by nine months, was welcome and he hoped that Members could reach an agreement by that target date. Allowing the situation of uncertainty to continue could only damage the credibility of the Organization.

99. With regard to the content of the amendment, especially the status of the Chairman's Statement, Korea fully shared the views expressed by the delegation of the European Communities. He added that Korea opposed any amendment exercise that would change the voluntary nature of the commitment that the so-called "opt-out" countries had made in the process of agreeing to the decision in August 2003. Finally, he said he was flexible as to the form of the amendment as long as Korea's interests were satisfactorily accommodated in the content of the amendment.

100. The representative of Malaysia said that her delegation could agree with the Chairman's proposal that more time should be provided to the TRIPS Council to prepare the amendment in light of the need for further reflection by Members on the form and the content of the amendment. On the content of the amendment, she said it had been recognised that any amendment would have to be based on the Decision, where Members were of the view that it would be appropriate to do so. With regard to the form of the amendment, she agreed with the representative of Argentina that footnotes were not the customary approach to making an amendment. This could become an issue if the footnote was seen to be subordinate to the main legislation. The Council should consider other approaches than those based on a footnote. She shared the concerns of the delegation of Argentina regarding elevating the Chair's Statement through an amendment to the same legal status as the Decision.

101. In the light of the European Communities' view that the Chair's Statement would continue to be applicable in relation to the new TRIPS provision, she said that the Council would need to study carefully whether the Chairman's Statement would continue to have any status after the amendment. Finally, she joined others in expressing interest in the Canadian and Norwegian legislation implementing the paragraph 6 Decision and looked forward to their subsequent implementation.

102. The representative of Thailand said that, with respect to the issue of timing, there was no reason to rush into an amendment. He would like to see that the decision was workable in practice and, when it came to the amendment, it was important to make sure that it contained elements that

could really be implemented. Those elements that could create problems should be carefully considered and examined. He could accept the Chairman's proposal to extend the timeframe of the amendment to the end of March 2005.

103. The representative of Norway said that, during the previous meetings of the TRIPS Council, his delegation had reported progress in implementing the 30 August Decision. He said that on 14 May 2004, the Decision had been implemented into the Norwegian legislation through a set of regulations, which had entered into force on 1 June 2004. He said that his delegation intended to explain the system in more detail in a WTO document to be circulated in the near future, and that copies of the regulations and a set of explanations on the reasons behind such regulations had been distributed and were available at his Mission upon request.

104. The first legislative step in the internal process of Norway had been the amendment int December 2003 of a provision in the Patent Act that was to provide the legal basis for the executive branch to implement the Decision. At the same time, another provision of the Patent Act had been amended in order to allow not only courts but also the competition authorities to grant compulsory licences not only under the new system, but also in general in relation to any type of compulsory licence in other areas of science. A decision of the competition authority could always be challenged before the courts. A draft set of regulations had been circulated in January to the public for comments. He added that the adopted set of regulations aimed at reiterating the content of the Decision. He explained that this was part of a Norwegian tradition where national provisions relating to the implementation of international public law obligations followed the international public law provisions. He said that the set of regulations made necessary derogations from the export restrictions of Article 31(f) of the TRIPS Agreement, and also interpreted the concept of "adequate remuneration". The other provision of Article 31, as well as those of the Norwegian Patent Act, would continue to apply in relation to applications for compulsory licences under the system. For instance, he said, there was no change in the general requirement under TRIPS Article 31(b), meaning that unless there was a case of national emergency of public non-commercial use, prior efforts to negotiate an authorisation from the right holder on reasonable commercial terms and conditions should have been made.

105. He said that a main principle underlying the new set of Norwegian regulations was that producers that applied for a compulsory licence should have, as a point of departure, a legal right to obtain such a licence, provided that the conditions of the 30 August Decision and the TRIPS Agreement were fulfilled. For instance, Norwegian authorities should normally accept the quantity described in the notification unless there were specific indications that the need had been inaccurately described in the notification. This allowed increased predictability. Thus, if the importing State's request was based on public health considerations and fell within the scope of the Decision and the TRIPS Agreement, and if the products were to be produced solely for exports to fulfil that State's current needs, a compulsory licence should normally be issued.

106. There had been general support for the draft proposal in the consultation process. Possibly the most important outcome of the consultation process was the decision to put non-WTO Members on equal footing with WTO Members under the system. Another modification resulting from the consultation process had been the decision to specify in more detail the requirements of the Decision in paragraph 2(ii) that products must be clearly identified as being produced under the system. The regulations specifically stated that the production and export should cease if the products "to an appreciable degree" were used for purposes not in accordance with the conditions for granting the licence.

107. Norway did not have a large pharmaceutical industry, at least not in the product areas that were most likely to benefit from the Decision. Therefore, his delegation did not believe that the Norwegian industry would be an important contributor under the system in the near future. He explained that Norway's initiative to implement the Decision should instead be seen as a sign of

strong support in fulfilling the mandate given to the Council in the Doha Declaration on the TRIPS Agreement and Public Health. He further stated that the problems identified in the Doha Declaration were as serious as they had been three years before. Thus, his delegation believed that Canada and Norway's decisions to implement the 30 August Decision should be seen as important elements, among other efforts, to address global health problems and hoped that other Members would soon follow.

108. He said that his country's efforts also illustrated that a waiver might be a sufficient basis for implementing the system in the national legal order. Norway had since the very start of this process leading up to the 30 August Decision, advocated that the Decision should take the form of an amendment. He supported the Chairman's proposal as to how the Council should proceed on this issue, allowing more time in order reach an agreement on an amendment.

109. In his view, the amendment of the TRIPS Agreement was primarily a technical exercise. He was not committed to any particular form of an amendment, and was open to a footnote, which should not pose any legal problems. In his view, the Statement should be seen merely as an interpretative instrument and as a unilateral declaration that did not belong in the TRIPS Agreement.

110. The representative of Canada said that her delegation supported the Chairman's proposal on the issue of timing. She also informed the Council that, on 14 May 2004, Canada had passed legislation amending its Patent Act and Food and Drug Act to facilitate the export of low-cost pharmaceutical products to countries in need. This legislation would come into force in the fall of 2004 when the supporting regulations would have been promulgated. These regulations would be pre-published and open for public commentary at that time. She added that her delegation had prepared a short document that summarised Canada's legislation for those who would be interested.

111. The representative of India said that he was quite flexible on the extension of the timeframe for concluding the amendment process. Regarding the content of the amendment, he said that it was India's view that it should be based "as appropriate" on the 30 August Decision, and that the Chairman's Statement read out at the time of adoption of the Decision could not be incorporated in the amendment as it would upset the fine balance of rights and obligations contained in that Decision.

112. The representative of Hong Kong, China said that his delegation could support the Chairman's suggestion to extend the timeline to March 2005. While paragraph 11 of the Decision allowed some flexibility on the question of timing, he believed that it was important for the TRIPS Council to issue a decision on timing, as the end of June was approaching and the outside world was watching the work on this important issue with keen interest.

113. As to the substance of the amendment, he said that his delegation had all along advocated that this should be a purely technical exercise and Members were not there to renegotiate any elements in the package that had been agreed to in August. Different views had been heard on the status of the Statement, which reflected the delicate balance that had been achieved in August when the agreement on the Decision had been reached. This reinforced his belief that the amendment exercise should not attempt to change that balance and the status of either the Decision or the Statement.

114. The representative of Pakistan said that the process leading up to the 30 August Decision had been undoubtedly a gruelling one, and he was sure that other delegates that had been part in some way or the other in that process would never forget the give and take that had had to be done at that point in time to come to the Decision. He said that Members could not lose sight of the statements made from different Members which played part in bringing all the sides together in agreeing to this waiver decision.

115. He said that, with regard to the question of why the waiver had not been used in the last nine months of its operation, given the grave nature of the problem that it had been intended to address, the answer lay in the apprehensions of the proponents even at the time of agreeing to the waiver regarding the uncertainties arising out of the temporary nature of the measure itself. It could also be the nature of the obligations contained in the waiver which could have rendered the waiver up to this point a counter-productive instrument.

116. Finally, he said that his delegation had no problems in agreeing with the Chairman on the extended deadline of March 2005, given the fact that the actual waiver decision had also been delayed by the same time. He said that his delegation was very interested in the statement of the Argentine delegation. With regard to the content of an amendment, he believed that it should be governed by the relevant paragraph of the Decision which used the wording "where appropriate".

117. The representative of the European Communities, referring to the comments made by Kenya, sought further clarification since he had not understood why it was not easy to make a notification. Was this because, due to some internal processes in Kenya, it was not easy to identify the type of illnesses that needed to be tackled, the products that were needed, or potential generic producers of the product? If would be useful for Members to understand any difficulties that might have arisen so that they could be avoided by other Members wishing to make a notification.

118. By its nature, a waiver was intended to be temporary. It appeared that there was a misunderstanding as to whether this referred to the substance of the Decision or to its form. His understanding was that, while the temporary waiver should be made permanent through an amendment to the TRIPS Agreement, the content of the waiver was not of a temporary nature. What mattered was not whether the amendment would be made by a footnote or not, but what the amendment would actually say. If the content of the amendment was clear to all delegations, some of them might be less concerned about whether it should be in a footnote or whether it should be in the body of the Agreement or in an annex to the Agreement. Noting that some delegations continued to refer to the "where appropriate" formula still nine months after the Decision had been adopted without indicating what might be appropriate or not, he said that it was time for delegations to clarify their positions. He disagreed with the view that Members could not act on the basis of the waiver, since it clearly allowed Members to act differently, provided that the conditions were met. The waiver gave the needed legal security to act upon, as had been done by Canada and Norway, and as was being done by Switzerland and the European Communities.

119. The representative of Brazil said that his delegation was in a position to join the consensus to extend the timeframe for concluding the work on an amendment to the TRIPS Agreement along the lines of the proposal made by the Chairman. He acknowledged the usefulness of the analysis of the delegation of Argentina on the legal significance of footnotes. In his view, it seemed inappropriate to use a footnote to amend the TRIPS Agreement and to include the Statement in the amendment.

120. The representative of China agreed with the Chairman's proposal to extend the deadline to March 2005. He was flexible as to the legal form of the amendment and was not against the footnote approach. This was without prejudice to any other approach that might be tabled. He was concerned about the ambiguity of the legal status of the Statement, and believed that some clarification of the legal status could be provided by the WTO Secretariat in written form.

121. The representative of the United States said that his delegation was fully committed to work with other Members in order to memorialise what had been agreed on 30 August 2003, including the Decision and the Statement, in an amendment of the TRIPS Agreement with a view to its immediate adoption. His delegation continued to believe that the Council should not re-open substantive issues and shared the view that this was merely a technical exercise. As to the Chairman's proposal concerning the timing of the amendment, he said his delegation could support a short and specific

timeframe for completing the work that maintained the flexibility contained in paragraph 11, and could, therefore, support the Chairman's proposal to extend the deadline to March 2005.

122. With regard to issues of form and content, he said that as a preliminary matter his delegation would not comment directly on a legal note produced by the Secretariat but that, regardless of the views of the United States on substance, his delegation shared the systemic concerns raised by the Philippine delegation. He said that, as a general matter, his delegation did not normally consider it appropriate or particularly helpful for the Secretariat to be developing extensive legal analysis and drawing conclusions. It was up to Members to interpret their WTO obligations.

123. His delegation strongly disagreed with the view that the Statement was merely a unilateral statement. He clarified that by its own terms the Statement contained key shared understandings of Members and such shared understandings were indeed an essential part of the Agreement of 30 August 2003. He said that there would have been no agreement in August 2003 without these shared understandings contained in the Statement. It seemed to his delegation that there might be a misunderstanding that the United States was trying to upgrade the status of the Chairman's Statement in some manner. However, as had been said before, what the United States sought was to preserve all aspects of the action taken on 30 August 2003, including the legal relationship between the Decision and the Statement. He said that his delegation remained open to the views of others on how the amendment process could be expeditiously accomplished. However, he believed, like the delegations of Japan and Switzerland, that this amendment must preserve the agreement reached in August and would therefore need to include an express reference to both the Decision and the Chairman's Statement.

124. The representative of Kenya said that before the adoption of the Decision his delegation had clearly been told that the Statement was meant to allay the fears of the pharmaceutical industry, and that he believed that this fear was behind them as was the statement.

125. The Chairman said that he wished to make it clear that the suggestion he had made did not exclude the TRIPS Council agreeing earlier than March 2005 and obviously he hoped that this would be the case. He also wished to make it clear that, in order to meet the new time-frame, the Council would need to work expeditiously and purposefully, starting with its September meeting. He said that he was sure that there was a readiness on the part of delegations to do this.

126. With regard to the way forward, he noted that there were many positive and supportive reactions to the proposal he had made, but that he had also noted that some groups still had to consult amongst themselves on this suggestion and, therefore, were not in a position to endorse it at the present meeting. He said that, as he had mentioned in the consultations he had held, he believed that it would be useful to keep the General Council informed of any new arrangements in the TRIPS Council for finalising work on the amendment. He noted that the General Council would not meet until the end of July. This would give time for these groups to coordinate. He asked these groups to let him know the outcome by the end of June. If they could join the other delegations in supporting the proposal that he had made, the TRIPS Council would be deemed to have agreed on it and he would inform the General Council accordingly.

127. The representative of the Philippines wondered whether the proposal which the Chair had read out earlier would be deemed to have been approved if the Members which were still in the process of consulting amongst themselves would communicate their consent to the Chairman, without the need for the TRIPS Council to meet again to approve this proposal. He added that it might be useful if the proposed language could be circulated to all Members. Also the representative of Argentina requested a clarification as to whether the Council would be deemed to have agreed on the proposal if there were no objections.

128. The Chairman confirmed that, if the groups which were still in the process of consulting amongst themselves could join other delegations in supporting the proposal, the Council would be deemed to have agreed on it. He added that, as requested by the delegation of the Philippines, he would circulate the proposal in writing to all Members.

129. The Council agreed to proceed as suggested by the Chair.[1]

I. REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

130. The Chairman recalled that, at its meeting in November 2003, the Council had taken up its first annual review of developed country Members' reports on their implementation of Article 66.2 of the TRIPS Agreement. This had been done pursuant to paragraph 2 of the Decision on the "Implementation of Article 66.2 of the TRIPS Agreement". At the Council's meeting in March 2004, his predecessor had offered an opportunity for Members to make further comments on the information submitted for the November meeting. Since then, the delegation of Zambia had requested that the matter be kept on the agenda of the present meeting so as to have an opportunity to comment on these reports. He said that the delegation of Zambia had just informed him that it was not in a position to provide comments at the present meeting but that the LDC group would like to provide its comments at the Council's meeting in September 2004. He added that, since the Council's meeting in March 2004, a further report had been received from Canada (IP/C/W/412/Add.7).

131. The representative of Tanzania confirmed that the LDC group intended to present its written comments at the Council's next meeting in September 2004.

132. Turning to the arrangements for the Council's second review under the Decision, the Chairman recalled that its paragraph 1 provided that developed country Members shall submit annually reports on actions taken or planned in pursuance of their commitments under Article 66.2. To this end, they must provide new detailed reports every third year and, in the intervening years, provide updates to their most recent reports. These reports must be submitted prior to the last Council meeting scheduled for the year in question. Paragraph 3 of the Decision determined the information that must be provided in these reports. The first set of detailed annual reports under the Decision had been presented to the Council's meeting in November 2003. Therefore, in 2004, developed country Members should submit updates to these reports prior to the Council's end-of-year meeting that had been scheduled for 30 November through 2 December. As provided in paragraph 2 of the Decision, the Council should review these updates at that meeting. Accordingly, he suggested that developed country Members be requested to submit updates to the reports they had provided last year on actions they had taken or planned in pursuance of their commitments under Article 66.2 by 9 November, i.e. three weeks before the meeting, in order to allow their timely circulation and review at the Council's meeting in November.

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

[1] The language proposed by the Chair on the question of the timing of the further work on the amendment was circulated to Members by fax, dated 17 June 2004. Subsequently, the Chair informed Members, in a fax dated 2 July 2004, that the groups that had had to consult amongst themselves on this suggestion had informed him that they could join other delegations in supporting his proposal. He indicated that he would thus inform the General Council, at its meeting scheduled for 27-28 July, of the arrangements for the further work of the TRIPS Council on this matter.

J. TECHNICAL COOPERATION AND CAPACITY-BUILDING

(i) Annual updates on technical cooperation activities

134. The Chairman recalled that, in 2003, the Council had taken up its annual review of technical cooperation at its meeting in November. In preparation for this, developed country Members, intergovernmental organizations with observer status in the Council and the WTO Secretariat had updated information on their technical cooperation activities relevant to the implementation of the TRIPS Agreement. Since the Council's meeting in March 2004, a further report had been received from the World Health Organization, which focused on the WHO's technical and financial cooperation programmes relevant to TRIPS implementation and access to drugs (IP/C/W/407/Add.4).

135. Turning to the arrangements for this year's annual review of technical cooperation, he said that the Council had traditionally undertaken this review at its September meeting, but last year it had been done at the Council's November meeting, since no meeting had been scheduled for September due to the Cancún Ministerial Conference. He suggested that the Council once more invite developed country Members to supply information on their activities pursuant to Article 67 of the TRIPS Agreement. Other Members who also made available technical cooperation were encouraged to share information on these activities if they so wished. He also suggested that the Council once more invite those intergovernmental organizations that had observer status in the TRIPS Council to provide information on their activities of relevance and that the WTO Secretariat might also be instructed to report on its activities.

136. He then sought the Council's view on whether it should hold this year's review in September, as had been done in the past, or whether Members would prefer to hold the review one year after the last review, i.e. at the Council's November meeting. If Members would agree to hold the review again in September 2004, he suggested that the Council request that the information be made available by the end of August, in order to allow its timely circulation before the meeting.

137. The Council agreed to hold the review at its meeting scheduled from 21 to 23 September 2004 and proceed as suggested by the Chair.

(ii) Joint Initiative

138. The Chairman recalled that the WIPO and WTO Secretariats had launched, on 14 June 2001, 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.

139. The representative of the Secretariat informed the Council about two forthcoming national seminars that it was organizing jointly with WIPO, one in Myanmar in June and the other in Chad in August 2004. He said that the Secretariat was working on mutually agreeable arrangements with WIPO and host countries for national seminars in Ethiopia, Niger and Uganda to be held later in 2004. In addition to these joint activities with WIPO, he said that the Secretariat would be holding, at the request of these LDC Members, national seminars in Benin in July, Bangladesh in August, and Nepal in September 2004.

140. As regards other technical cooperation activities, the Secretariat was in the process of holding regional workshops on certain topical issues, including the TRIPS Agreement and public health, particularly the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, biotechnology, biodiversity, traditional knowledge and folklore, geographical indications, and enforcement. The Secretariat had already organized two such workshops, one in Kuala Lumpur, Malaysia in April for Asian and the Pacific economies, and the other in Johannesburg, South Africa in June 2004 for English-speaking African countries. These workshops had benefited from contributions by speakers from WIPO and the WHO, as well as by

delegates from developed and developing country Members who represented their countries in the TRIPS Council and, therefore, had full first-hand experience of these matters. He thanked the Malaysian and the South African authorities for their cooperation in the organization of these eventsas well as the Secretariats of WIPO and the WHO, as well as the delegations in question for making available speakers for these events. He informed the Council that the next such regional workshop would be held in Yaoundé, Cameroon in July for French-speaking African countries. The Secretariat was planning to organize jointly with WIPO another regional workshop in Moldova in October, and other activities in Latin America and the Caribbean in the final month of the year. The Secretariat would make a full report on its technical cooperation activities for the Council's September meeting.

141. The representative of WIPO joined the representative of the WTO in thanking the authorities of the countries that had hosted WIPO's and the WTO's joint activities.

142. The Council took note of the statements.

K. INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

Accessions

143. The Chairman informed the Council that the Kingdom of Nepal had become the 147th Member of the WTO on 23 April 2004. Nepal was the first least-developed country that had joined the WTO pursuant to Article XII of the WTO Agreement, i.e., through the full WTO working party process.

L. OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

144. 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.

145. The representative of Brazil said that an important item on the Council's agenda was the relationship between the TRIPS Agreement and the CBD. During the earlier discussions, the Chair had noted that there was general willingness in the Council to have a more focused and structured discussion on the three related agenda items, i.e., the review of the provisions of Article 27.3(b), the relationship between the TRIPS Agreement and the CBD, and protection of traditional knowledge and folklore. He noted that the Conference of the Parties of the CBD, held in February 2004, had adopted a decision on access and benefit-sharing as related to genetic resources. He believed that it would be beneficial to the Council's discussion on the relationship between the TRIPS Agreement and the CBD to grant the Secretariat of the CBD observer status. Therefore, he reiterated his delegation's proposal that the Council consider granting the CBD observer status at the Council's forthcoming meeting.

146. The representative of the United States said that he could not agree to grant the Secretariat of the CBD observer status for two reasons. First, the issue of observer status must be dealt with under appropriate guidelines to be established by the General Council. Unfortunately, it had not yet established such guidelines. Second, Members should also consider the breadth of interest that an intergovernmental organization had in the issues dealt with by the TRIPS Council. The Secretariat of the CBD had a limited interest in the TRIPS Agreement, which was not sufficient for granting observer status.

147. The Chairman suggested that the Council agree to revert to the matter at its next meeting.

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

M. OTHER BUSINESS

149. The Chairman informed the Council that his authorities in Hong Kong, China had announced that he would return to Hong Kong, China after the summer to take up a new appointment. He said that he had informed the Chair of the General Council of this development and that it was his understanding that the Chair intended to conduct consultations shortly on the chairmanship of the TRIPS Council. He thanked the Secretariat and all the delegations for their support and full cooperation during his chairmanship.

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