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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

Held in the Centre William Rappard on 14-15 June 2006

Chairman: Ambassador C. Trevor Clarke (Barbados)

The present document contains the record of the discussion which took place during the TRIPS Council meeting held on 14-15 June 2006.

Subjects discussed — Page nos.

1. In proposing the agenda for adoption, the Chairman said that item J on "Enforcement of Intellectual Property Rights – Communication from the European Communities" had been put on the proposed agenda at the written request of the delegation of the European Communities, dated 10 May 2006. He proposed that the Council adopt the agenda as proposed.

2. The Council so agreed.

A. NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

3. The Chairman informed the Council that, since its meeting in March, the Council had received a number of supplements and updates to earlier notifications of laws and regulations notified under Article 63.2 of the Agreement. Finland had provided a complete update to its notification of laws and regulations, including its responses to the Checklist of Issues on Enforcement; Japan had notified an updated text of the Japanese Patent Law and certain other regulations; the Kyrgyz Republic had notified a number of main dedicated and other intellectual property laws and regulations; Qatar had notified its laws on trade secrets and layout-designs of integrated circuits; and Sweden had notified amendments to its International Copyright Regulation. The European Communities had notified a regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. These notifications were being circulated in the IP/N/1/- series of documents. He urged those Members whose initial notifications remained incomplete to submit the outstanding material without delay, and reminded other Members of their obligation to notify any subsequent amendments of their laws and regulations without delay after their entry into force. In particular, he reminded those Members who had made any changes to their laws and/or regulations to implement the decision on "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" and who had not yet notified such changes to the Council to do so.

4. With regard to notifications of contact points under Article 69, he said that, since the Council's meeting in March, an update to a contact point notified earlier had been received from Slovenia. This notification had been circulated in document IP/N/3/Rev.9/Add.2. To date, 121 Members had notified contact points under Article 69.

5. The representative of the European Communities said that Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems had been published in the Official Journal of the European Union on 9 June 2006, and that it would enter into force on 29 June 2006. With this Regulation, the European Communities had created a legal basis for the granting of compulsory licences for export purposes, as foreseen in the WTO General Council Decisions of 30 August 2003 and 6 December 2005. He hoped that this Regulation would contribute to making key medicines more easily available to countries not disposing of sufficient production capacities in the pharmaceutical sector.

6. The aim of the Regulation was to transpose the WTO General Council Decisions faithfully and completely, without any restrictions or unnecessary burdens. It contained provisions preventing the re-import of products exported under a compulsory licence. Like a contractual licence, a compulsory licence created a contractual bond between the patent holder and the licensee, with the sole but important difference that the will of the patent holder was substituted by a decision of the public authority. The Regulation set out in detail the obligations of the licensee towards the patent holder.

7. The Council took note of the statements made.

B. REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

(i) Follow-up to reviews already undertaken

8. The Chairman said that, with regard to the reviews of national implementing legislation that had been initiated at the Council's meetings since April 2001, eight reviews still remained on the Council's agenda. These reviews concerned Cuba; Fiji; Grenada; Mauritius; Saint Kitts and Nevis; Saint Vincent and the Grenadines; Suriname; and Swaziland. As requested by the Council at its last meeting, the Secretariat had written to the delegations in question to remind them of the outstanding questions.

9. The Secretariat had received a communication from Suriname, in which it had indicated that its Draft Law on Industrial Property was still with Parliament for approval. A draft law on copyright had been prepared, and it was still working on a draft law on neighbouring rights. Consequently, Suriname had indicated that it was still not in a position to provide responses to the questions posed to it in the context of the review, and that it wished to ensure that it would make every effort to submit all the outstanding material before the Council's next meeting.

10. The representative of Mauritius said that the lateness in providing the information was due to the fact that the Government was trying to bring in a number of amendments in various laws. Furthermore, there had been some reorganization, namely that the Ministry of Art and Culture had taken charge of the Copyright Unit. His delegation undertook to do its best to provide the information within a short span of time.

11. The representative of Cuba said that the information her delegation had provided earlier to the Council on its responses was still current. The responses had not been sent yet, since four pieces of legislation were still being drafted. They were on a list of priorities and had to be approved by the government authorities. It was not yet possible to provide information regarding the date on which this legislation would be approved, but she hoped that the matter would be solved in the second half of the year.

12. The representative of Fiji said that his delegation had contacted the capital concerning the outstanding questions. It had assured him that the responses would be forthcoming in the very near future, hopefully before the Council's next meeting.

13. The Chairman said that a number of questions had also been raised with regard to the implementing legislation of certain 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. These Members were Dominica, Gabon, Ghana and Guyana. As requested by the Council at its last meeting, the Secretariat had also written to these delegations to remind them of the outstanding questions.

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

(ii) Arrangements for the review of national implementing legislation of Saudi Arabia

15. The Chairman recalled that, at its last meeting, the Council had agreed that it would take up the review of TRIPS implementing legislation of Saudi Arabia, a newly acceded Member, at its first meeting in 2007, and that it would come back to the arrangements for this review, in particular the deadline for questions and responses, at the present meeting. As requested by the Council, the Secretariat had been in contact with the delegation of Saudi Arabia to draw its attention to the TRIPS obligations relating to the notification of implementing legislation.

16. The representative of Saudi Arabia said that the notification of Saudi Arabia's IPR laws and regulations was under preparation and that it would be submitted to the TRIPS Council soon, not later than the end of July.

17. The Chairman said that the Council's first meeting in 2007 had not yet been scheduled, but that he expected it to take place, as usual, in February or early March. Using this approximate date, and in accordance with the standard procedures for the review of legislation, he proposed that the Council set the following target dates for the submission of questions and answers in this review:

- questions should be submitted to Saudi Arabia, with a copy to the Secretariat, by 27 November 2006; and

- responses to questions posed within that deadline should be submitted by 8 January 2007.

18. 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

19. The Chairman recalled that, at its last meeting, the Council had agreed to maintain its present method of work on these matters at this stage, and to keep this method under review to assess whether any change might prove appropriate in the light of developments. As suggested by the Chairman, the Council continued its past practice of discussing these three agenda items together, on the basis of the contributions by Members.

20. In addition to recording the discussions in the formal session of the Council, the minutes below on these items also reflect, as agreed to by the Council, additional points made by certain delegations in the informal consultations held on the TRIPS Agreement and the CBD as an outstanding implementation issue by Deputy Director-General, Rufus Yerxa, on 6 and 14 June 2006.

21. He recalled that two new documents had been presented to the Council's March meeting: one from the United States, (IP/C/W/469); and another from Cuba, Ecuador, India, Sri Lanka and Thailand, which had been made available as an advance copy. Since the meeting, Bolivia had requested to be added to the list of co-sponsors. This addition had been made to the document before its circulation as document IP/C/W/470. As these two documents had been made available just prior to that meeting, some delegations had indicated that they intended to make further comments on them at the present meeting. The Council had received two new communications, one from Japan, (IP/C/W/472); and another from Norway (IP/C/W/473, WT/GC/W/566 and TN/C/W/42).

22. Introducing document IP/C/W/472, the representative of Japan said that the communication contained in its annex had also been submitted to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The document consisted of four parts: the relationship between the Convention on Biological Diversity (CBD) and the patent system; efforts made by Japan in pursuing the objectives of the CBD; the establishment of databases on genetic resources or traditional knowledge to prevent erroneously granted patents; and the study of the disclosure requirement. He said that the CBD and the patent system were complementary to each other. The patent system conferred protection to inventions that met the stipulated criteria rather than to matters that existed in the public domain, such as traditional

knowledge or genetic resources. The patent system thus provided an important incentive for innovation and technology transfer, and should not be changed on account of the provisions of the CBD.

23. As a party to the CBD, Japan had been actively involved in pursuing its objectives. Japan had established "Biotechnological Strategies" and "Guidelines on Access to Genetic Resources for Users in Japan" to encourage private companies and researchers to comply with the CBD and the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines). The Japanese Bioindustry Association (JBA) had conducted training programmes to promote the CBD. The National Institute of Technology and Evaluation (NITE), a biological resource centre in Japan, had been promoting joint research projects with other Asian countries in compliance with the CBD requirements of access and benefit sharing and prior informed consent.

24. Japan shared some Members' concerns on erroneously granted patents. It was his delegation's view that building databases of genetic resources and traditional knowledge that would be easily accessible to examiners would be effective to prevent such a problem. In the paper it was suggested that a summary, written in a language that most examiners could understand, be attached to documents written in indigenous languages. This would enable patent examiners to utilize databases on a one-stop-research basis.

25. Regarding the requirement of disclosure of origin, prior informed consent or benefit sharing, he said that this requirement would not help to prevent erroneously granted patents, because patent examiners had to research technical information with respect to novelty and inventive step regardless of the country of origin or source.

26. Introducing document IP/C/W/473, the representative of Norway said that he believed there was a consensus between WTO Members that the TRIPS Agreement and the CBD could and should be implemented in a mutually supportive manner. His delegation had identified no inconsistency between the two treaties, but believed that interaction between the two would be enhanced by introducing an obligation in the TRIPS Agreement to disclose the origin of genetic resources and traditional knowledge. Such a disclosure obligation would facilitate the enforcement of Members' rights over their genetic resources that were the subject of a patent application, and would make the CBD provisions on prior informed consent and benefit sharing more effective. Furthermore, he said that the disclosure obligation should go beyond the scope of the CBD; that is, it should also apply to traditional knowledge which was not directly linked to genetic resources. Such a requirement could also help the examination of the novelty and inventive step of the invention, thus helping to prevent the issuance of erroneous patents.

27. The disclosure obligation should be based on certain key principles. First, patent applicants should be obliged to disclose information on the supplier country of genetic resources and traditional knowledge - and the country of origin, if known and different from the supplier country - in their applications. If the national law of the supplier country or country of origin required consent for access to genetic resources or traditional knowledge, the disclosure obligation should also encompass a duty to state whether such consent had been given. If the country of origin was unknown, that fact should be disclosed. Second, the disclosure obligation should apply to all patent applications at the international, regional, and national levels. An identical disclosure requirement should thus be reflected in other international instruments, such as WIPO treaties or regional or bilateral agreements. Third, if the applicant was unable or refused to give information, the application should not be allowed to proceed. At the application stage, non-compliance with this obligation should be treated as a breach of a formal requirement so that the application should not be processed until the required information had been submitted.

28. Fourth, if a breach of the disclosure obligation was discovered only after the patent had been granted, it should not in itself affect the validity of the patent. Such a breach should be subject to appropriate and effective sanctions outside the patent system, for example criminal or administrative penalties. Upholding post-grant patent protection despite non-compliance with the disclosure obligation was important to avoid creating unnecessary uncertainty in the patent system. Revoking a patent as a consequence of non-compliance with the disclosure obligation would not benefit those who considered themselves to be entitled to share the benefits arising from the invention because patent revocation would negate the exclusive rights from which benefits could be derived. Yet, a patent could be revoked if the substantive patentability criteria had not been met. Fifth, in order to increase transparency, a simple notification system should be introduced under which patent offices would send all declarations of origin that they received to the CBD Clearing-House Mechanism. Furthermore, he said that such a disclosure obligation would be most appropriate in a new provision following Article 29 of the TRIPS Agreement.

29. In conclusion, he said that his delegation supported the amendment of the TRIPS Agreement to introduce an obligation to disclose the source and origin of genetic resources and traditional knowledge in patent applications. His delegation was ready to engage in text-based negotiations with a view to adopting such an amendment as soon as possible.

30. The representative of India requested that the communication from Brazil, China, Cuba, India, Pakistan, Peru, Thailand and Tanzania to the General Council and the Trade Negotiations Committee, circulated as document WT/GC/W/564/Rev.1 and TN/C/W/41/Rev.1, also be circulated as a TRIPS Council working document.[1] He drew the attention of the Japanese delegation to the several contributions made by developing countries which he said refuted the course of action suggested by Japan.

31. He said that Norway's proposal showed its recognition of the development dimension of the disclosure issue, which was in accordance with the instructions contained in paragraph 3 of the airgram convening the meeting. His delegation was ready to engage in text-based negotiations based on all proposals on the disclosure requirement in the TRIPS Council or other bodies of the WTO. He said that, being put forward by a developed country, the proposal showed growing convergence on the need for mutual supportiveness of the TRIPS Agreement and the CBD, and on a TRIPS amendment being the appropriate solution for the end of July 2006. The proposal recognized the need for a substantive obligation on patent applicants to disclose the source and country of origin of genetic resources and traditional knowledge, evidence of prior informed consent and benefit sharing. The failure to comply with such an obligation would be punished. It also recognized the need for consultations to develop a text for further negotiations.

32. Turning to the US submission (IP/C/W/469), he said that he appreciated the continued US engagement on these issues. He said that he was happy to note that, despite not having ratified the CBD, the United States shared the objectives of the CBD and was ready to take steps to implement such objectives at the national level. He said that the US had asserted that the absence of provisions against misappropriation in the TRIPS Agreement did not indicate conflict with the CBD, that it was not the lack of safeguards in the Agreement that led to erroneous patents but the lack of national systems to regulate the use of genetic resources, and that the disclosure proposal would create legal uncertainty and other negative consequences. He responded that the absence of such provisions against misappropriation in the Agreement promoted the grant of patents based on genetic resources and associated traditional knowledge without recognizing the CBD objectives, highlighting the urgent need for action towards mutual supportiveness of the two instruments in line with the instructions contained in Article 16.4 of the CBD. Unless the CBD objectives were integrated within the patent

[1] Subsequently circulated as document WT/GC/W/564/Rev.2, TN/C/W/41/Rev.2 and IP/C/W/474, with the addition of Colombia as a co-sponsor.

system, these two instruments would run counter to each other. The objective of ongoing efforts was to establish adequate procedural norms within the TRIPS Agreement to prevent bad patents, to prohibit misappropriation, and to ensure that the private rights created through the Agreement did not trump the benefit-sharing mechanisms set up by governments in implementing their CBD obligations.

33. Article 29 of the Agreement stipulated certain minimum procedural requirements before the grant of patents. Developing countries were demanding that these procedures be supportive of the objectives of the CBD. These demands were in consonance with Article 7 of the Agreement, which called for the protection of intellectual property rights in a manner conducive to enhancing social and economic welfare. He further said that one of the aims of the disclosure requirements was to ensure that patents were only granted over those inventions which fulfilled the criteria of novelty and inventive step. Such requirements gave useful parameters of existing prior art that would help patent offices to establish inventiveness. This objective could be achieved only through incorporating the disclosure requirements in the Agreement, and not through domestic contract-based access and benefit-sharing regimes, as they only governed the conditions of access and benefit sharing. The disclosure requirement would also help patent offices identify the holder of genetic resources or the country of origin and ensure that the knowledge was not misappropriated.

34. Other solutions, such as searchable organized databases, post-grant opposition and re-examination procedures as suggested by the United States, were costly, inadequate and ineffective considering the unique nature of inventions based on genetic resources and associated traditional knowledge. Further, given that holders of genetic resources and traditional knowledge were highly dispersed, organized databases were not probable in the short term. Therefore, this was an impractical suggestion. In any case, oral traditional knowledge could not be included in databases in the short term. Post-grant opposition and re-examination proceedings were time consuming and unaffordable for the poor and disadvantaged resource holders.

35. He said that he appreciated the US acceptance of a requirement to disclose information material to patentability. An international disclosure obligation would be material to patentability and would help patent examiners in their search of prior art, and would prevent bad patents by adding to existing searchable databases. It would give useful hints to the patent office in ascertaining novelty and non-obviousness and indicate the country which needed to benefit from the commercialization of genetic resources. It was important to trace the true existing knowledge taken from the holder of traditional knowledge in order to establish the inventive step and ensure that bad patents were not issued. This would also ensure that due credit and benefits were given to such holders in cases where the new invention was based on the information provided by them. Thus the disclosure requirement was an effective way to ensure the mutual supportiveness of the TRIPS Agreement and the CBD as it provided a means to prevent misappropriation through patents granted without ensuring benefits to the providing country.

36. There might be different ways in which misappropriation of genetic resources and associated traditional knowledge took place. When there was misappropriation through patenting, bypassing the domestic access and benefit-sharing law, it was not possible to provide effective remedies through domestic law to prevent the abuse of the patent system when the use of such resources or knowledge took place beyond the borders of the providing country. Remedies should be found within the patent system of the country which had issued such a patent. The national system could not remedy such patents even through the terms of a contract and the only solution was to introduce the disclosure requirements at the international level.

37. Regarding the enforcement of national access and benefit-sharing provisions, he recalled that his delegation had illustrated the challenges through the "*Yahoo!-Nazi*" case in document IP/C/W/459. This case suggested that unless there was an international mandate, a country would have no obligation to enforce the terms of a contract or a decision upholding such terms when it was against

its domestic laws and public policy. This clearly showed that unless domestic access and benefit-sharing regimes were under an umbrella of an international obligation, the international character and outlook of the national regimes would not help to achieve the desired enforcement.

38. With regard to the US statement that the disclosure requirement could not be justified by its primary aim of preventing bad patents, he said that, if the source and country of origin were disclosed, the patent office could process the patent application on the presumption that the access obtained from the country of origin was legal. This requirement would ensure the flow of benefits to the providing country, thereby recognizing its proprietary rights over genetic resources and associated traditional knowledge.

39. Responding to the US argument that patent examiners might or might not seek additional information based on the "hints" provided by the disclosure requirements in light of their negative consequences, he said that once an international obligation was created, each country would take steps to improve its examination system. Thus, the disclosure requirements would prove to be sufficient to deal with the core concerns of developing countries. It would facilitate the compatibility of the TRIPS Agreement with the CBD and add to the strength, credibility and certainty of the patent system. On the other hand, domestic contract systems, unenforceable in many ways, could not achieve the efficacy of the disclosure requirements.

40. The representative of Chinese Taipei said that his delegation had not yet decided its position on the CBD issue. He posed the following questions to the co-sponsors of document WT/GC/W/564/Rev.1 regarding the draft amendment: whether the co-sponsors suggested that WTO Members not party to the CBD should comply with it; what the definitions of the terms "biological resources", "traditional knowledge", "derived from", and "developed with" were; who the provider would be if, for example, the applicant bought a potato in the domestic market and with whom the patent applicant would have to share benefits; whether the obligation to supplement and correct the information, as required by the third paragraph of draft Article 29*bis*, would exist both before and after the patent was granted; what would happen if Members did not have provisions on unenforceability of patents in their patent systems; and if a third party would seek the cancellation of a patent after finding falsely disclosed information in a patent specification, should the patent office allow the patentee to correct the information or revoke the patent directly? He said that since there was no international body or mechanism to verify the information disclosed by the patent applicant, it would be a great burden on patent examiners to review the fulfilment of the disclosure requirement. There should be a balanced mechanism to ensure that the owner of genetic resources and traditional knowledge received the benefits arising from the use of such resources and knowledge, that the inventor had the incentive to make innovations, and that the patent system had legal certainty without undue burdens on both patent examiners and patent applicants. In conclusion, he said that Chinese Taipei was in the process of formulating its own access and benefit sharing regime and was therefore interested in knowing about other Members' national experiences in this regard.

41. The representative of Sri Lanka said that the work in the WTO on the relationship between the TRIPS Agreement and the CBD had reached an advanced stage. His delegation supported the disclosure proposals put forward by a group of developing countries and the European Communities, and was in favour of commencing text-based negotiations to amend the TRIPS Agreement.

42. The representative of Brazil supported the request made by India that document WT/GC/W/564/Rev.1 and TN/C/W/41/Rev.1 be circulated as a TRIPS Council document. He said that the proposed amendment of the TRIPS Agreement was supported by the broad majority of developing countries. It was fully compatible with the Doha mandate and would be an essential outcome of the Doha Development Round. He said that the amendment had to be understood to be pro-intellectual property, as its objective was not to destroy, water down or encumber the intellectual property system in the TRIPS Agreement. Instead, it sought to make the system more robust in

general and better suited to the moral principles on which intellectual property protection should stand. Its objective was also to reduce the margin for misappropriation of biological resources and/or associated traditional knowledge. He said that immoral conduct should not be rewarded, and that patents should not be granted to inventions which were obtained through dishonest practices. He said that the amendment would show that the international intellectual property system was responsive to the particular needs and concerns of developing countries, in particular the mega-biodiverse ones among them. It would also make the patent system stronger by making the monitoring of dishonest practices viable and enforceable internationally. The amendment was compatible with the evolving nature of science and technology, especially biotechnology.

43. He further said that his delegation's position and responses to the technical questions posed by other Members could be found in documents IP/C/W/420, 429, 438, 442, 443 and 459. In view of the length of the time devoted to technical discussions and exchange of views, the time was ripe for moving beyond general statements into text-based negotiations, which would give effect to the instruction given to Members by Ministers.

44. He said that the disclosure requirements would not pose additional burdens for patent applicants and should not be considered as a new fourth patentability criterion. Non-compliance with the disclosure requirements would produce the proportional effect of preventing patent examination from proceeding. It could also constitute a ground for invalidation and revocation of patents. Members would be called upon to ensure effective enforcement procedures. Publishing the disclosed information would allow Members to track and enforce their rights over biological resources and traditional knowledge. It would be in line with other measures which had the aim of providing transparency within the international patent system.

45. He said that the establishment of databases, as suggested by Japan, for widespread use by patent examiners and interested Members, would lead to the misappropriation of traditional knowledge in the absence of mandatory disclosure requirements. Thus, it would not meet the interests of those who tried to find a solution within the patent system to safeguard their legitimate interests over traditional knowledge and those who wished to safeguard, through the intellectual property system, their sovereign rights over biological resources under the CBD.

46. He said that Norway's proposal and the proposal by the developing countries converged at several points, such as in the perception that the mutual supportiveness of the TRIPS Agreement and the CBD could be enhanced by an amendment to the TRIPS Agreement; the need for text-based negotiations and the mandatory nature of disclosure requirement. According to him, the suggestion that traditional knowledge by itself be the object of a disclosure requirement seemed to go beyond the developing countries' proposal, and he was interested in knowing how this would apply.

47. With respect to the US proposal on the national contract-based approach, he said that this approach would not provide legal certainty to those combating biopiracy because national legislations varied and the private nature of the contract would not create international obligations. The approach was also costly, burdensome, time-consuming and ineffective to tackle biopiracy and would not address the international dimension of the problem. Therefore, it was outside the scope of the Members' mandate, which was to look at the interface between the CBD and the TRIPS Agreement.

48. The draft amendment of the TRIPS Agreement contained in document WT/GC/W/564/Rev.1 attempted to translate a negotiating objective of the Doha Round into treaty language. Among the outstanding implementation issues, the issue of misappropriation of biological resources and associated traditional knowledge or biopiracy had the clearest and broadest support of the developing countries as a whole, and had matured both politically and technically to the extent that the proponents found themselves not only in a position to respond to all technical questions put forth by other Members but also in a position to propose a concrete text. The efforts to arrive at a concerted

position regarding language for an amendment highlighted the political and economic importance developing countries had attributed to the issue. This was part of the balance that could be brought to bear on the intellectual property system so that developing countries' concerns could be addressed through a solution that would be ingrained in the intellectual property system. Developing countries were demanding a system which provided protection to countries that were recognized by the CBD as the sovereign owners of their biological resources and to communities that were the holders of associated traditional knowledge. The issue of misappropriation was not different in the area of copyright or patent protection. The draft amendment was in line with other demands for adjusting to the ever changing nature of science and technology, such as the protection of broadcasting signals in new digital media or the WIPO Internet treaties of 1996.

49. He said that some Members believed that the CBD issue was not part of the negotiating mandate of the Doha Round, which in his view was not supportive of Members' common objective of achieving a development-oriented round. The Round should fulfil the expectations of the majority of developing countries and take their views, needs and requirements into account.

50. Regarding Switzerland's proposal, he said that it had been put forth in the WIPO Working Group on Reform of the Patent Co-operation Treaty, the IGC and the TRIPS Council. In his view, Members should focus their attention on a single forum, and the most appropriate forum was the WTO. Regarding Australia's concern about the potential misuse of the disclosure requirements by lawyers, he said that these requirements provided an easier solution to the problem of misappropriation than the contract-based approach, which might cause a higher risk of misuse.

51. He said that he had responded to 17 questions posed earlier by Members regarding the draft amendment of the TRIPS Agreement, and requested the Secretariat to circulate the responses as a TRIPS Council document[2] Regarding a question from Switzerland about the disclosure of information, he said that there was a clear need to disclose the country providing the resource as well as the source, and that the requirement to disclose the country of origin would be subject to the condition of "reasonable inquiry". Disclosing only the source without indicating the providing country would not achieve the objectives of the amendment. For example, the indication of source as a laboratory of a multinational company would give no clue about who had provided the resource. As the CBD gave the definitions of both "country of origin" and "the providing country", disclosing information on both of them was an essential requisite for the patent system to become supportive of the CBD. Disclosure of information on the providing country and country of origin would address the international dimension of the misappropriation issue; that is, patent rights might be conferred in a country which was different from the country where the resource was obtained.

52. Regarding a question from the EC and the Philippines as to why the term "biological resources" had been used instead of "genetic resources", he said that the CBD recognized that states had the sovereign right to exploit their own resources, in accordance with the Charter of the United Nations and the principles of international law. Thus, the power enjoyed by states was not limited to the regulation of genetic resources. Accordingly, Article 15 of the CBD, which addressed access to genetic resources, should not be interpreted as preventing states from regulating access and benefit sharing relating to biological resources. Furthermore, the use of the term "biological resources", which was broader than the term "genetic resources", was intended to ensure that all possible cases of biopiracy were covered and to keep pace with technological developments, especially with respect to biotechnology. The term "biological resources" was similar to the term "biological material" used in the preambular paragraph 27 of the European Directive on the Legal Protection of Biotechnological Inventions (Directive No. 98/44/EC), which was defined in Article 2 of the Directive. He further said that once Members had reached an agreement on the amendment, the definition of the term should be universal and binding on all Members.

[2] Subsequently circulated as document IP/C/W/475.

53. Regarding another question from the EC and the Philippines about who would decide the fulfilment of "reasonable inquiry" as contemplated under paragraph 2 of the draft Article *29bis* and what "reasonable inquiry" meant, he said that "reasonable inquiry" was similar to the expressions "reasonable efforts", "reasonable ground to know", and "reasonable steps under the circumstances" used in Articles 34, 37 and 39 of the TRIPS Agreement and in Members' national legislations. The applicant would initially determine how to satisfy this requirement, which was generally understood to mean due diligence. The role of patent offices would be limited, in principle, to confirming that patent applications disclosed information in the prescribed form.

54. He responded to several other questions posed by the EC. As to how the three triggers referred to in the draft amendment - that is, "concerns", "derived from" and "developed with" - would work or what they would mean in practice, he said that the three triggers sought to encompass relevant situations in which biological resources and/or associated traditional knowledge had contributed to an invention, while providing the margin of flexibility for national competent authorities where the patent would be sought to decide whether or not the applicant had complied with the rule. The term "concerns" referred to cases where a predominant or substantial part of an invention incorporated genetic resources. This usage would be similar to Article 3.1 of the EC Directive. The term "developed with" meant that an invention might not necessarily incorporate a genetic resource but the resource and/or associated traditional knowledge might be critical in the development of the invention. This would be the case particularly with respect to traditional knowledge as it might be rarely incorporated in the claimed invention but where the knowledge was indispensable in the development of the invention. The term "derived from" was intended to cover derivative inventions. It also appeared in Article 8.1 of the EC Directive referring to propagation or multiplication from original biological material.

55. With respect to whether the word "including" in the second sentence of paragraphs 2 and 3 of the draft Article 29*bis* meant that there were additional requirements other than the evidence of prior informed consent and access and benefit sharing, he replied in the negative.

56. About the meaning of the term "associated traditional knowledge", he said that the proponents of the draft amendment intended to give the ordinary meaning to this term. The word "associated" was prefixed to traditional knowledge in order to restrict the disclosure requirements to the traditional knowledge that had relevance to the biological resources used in developing the invention or concerning the subject-matter of the invention. In other words, not all forms of traditional knowledge were covered by the proposed disclosure requirements.

57. About the method of publishing the disclosed information, he said that it would be at the discretion of each Member. The information should be published simultaneously with the patent application or the granting of the patent, whichever was first, in the same or a separate document. The supplementary or corrected information required under paragraph 3 of the draft Article 29*bis* would be published separately.

58. Regarding questions from the EC and Chinese Taipei concerning the concept of "unenforceable" used in paragraph 5 of the draft Article 29*bis*, he said that unenforceability was presented as an alternative to the revocation of patents. Thus, a patent holder who had failed to comply with the disclosure requirements would not be entitled to go to court to enforce his rights. This was similar to the principle under the common law that the persons with "unclean hands" could not go to a court to demand equity. For example, if a patent holder did not pay the patent renewal fee, he could not go to court to enforce his patent rights.

59. With respect to New Zealand's question on why the substance of the draft text was broader than its title, he said that titles in the TRIPS Agreement, such as those of Articles 30 and 27, usually gave a general sense of the issue, but did not cover all the elements included under them.

60. He responded to several other questions from the Philippines and said that with regard to the transitional period for implementation of the draft amendment, the draft amendment was predominantly in the interest of developing countries and that the problem of biopiracy had not been tackled adequately for ten years since the entry into force of the TRIPS Agreement. Thus, the period between the adoption of the amendment and its ratification would be sufficient to allow countries to make the necessary changes in their laws. This would exclude LDCs, whose general transitional period had been extended to mid-2013 under the TRIPS Agreement, with possible additional extensions.

61. As to whether a declaration of the providing country and the source, together with a declaration that the providing countries did not have prior informed consent and access and benefit-sharing regimes, would suffice, he said that patent applicants should present the evidence of compliance with the applicable legal requirements in the providing country. If the providing country did not have such requirements, a declaration to this effect would suffice. He said that patent offices would not have to assess the validity of such declarations. It would work based on the prima facie assumption that the declaration had been provided correctly and in good faith. However, the patent applicant would still be required to disclose the providing country, from whom in that country the biological resource and/or associated traditional knowledge had been obtained, and, after reasonable inquiry, the country of origin.

62. Regarding another question about the application of the disclosure obligation, he said that it would apply only to patent applications that were submitted after Members' assumption of the obligation under the draft amendment. As to the meaning of "with reasonable grounds to know" used in paragraph 5 of the draft amendment, he said that the phrase was a widely used legal concept and could be found in many legislative provisions, such as Articles 44 and 45 of the TRIPS Agreement. Paragraph 1 of Article 44 provided, *inter alia*, that Members were not obliged to accord such authority in respect of protected subject-matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject-matter would entail the infringement of an intellectual property right. Similar language was used in paragraph 1 of Article 45 regarding damages. The words in paragraph 5 of the draft Article *29bis* would have a similar meaning to that in Articles 44 and 45. The knowledge of the patent applicant, the resource available to him, and normal business and scientific practices that he would be expected to know should be taken into account. For example, if there was an access and benefit-sharing law in the providing country, the patent applicant would be reasonably expected to know this law and its requirement. It also implied that the applicant was expected to exercise ordinary due diligence and not be reckless or careless.

63. As to whether Members could impose fees on patent applicants to cover the costs associated with the disclosure obligation, he said that it was anticipated that the disclosure obligation would not impose undue burdens and costs on patent applicants, patent holders or patent offices. For this reason, unless demonstrated otherwise, it was not foreseen that additional fees would need to be charged to cover the costs. However, where a Member considered it relevant, it could take this obligation, together with any other considerations, into account in setting fees. In essence, the intention of the proponents of the disclosure requirements was to leave this issue to the discretion of Members, subject to other rules in the TRIPS Agreement or other treaties, such as the Patent Cooperation Treaty.

64. He responded to several other questions from Chinese Taipei. As to whether paragraph 1 of the draft Article 29*bis* meant that a Member not party to the CBD would have to comply with CBD requirements, he said that paragraph 1 indicated broad objectives that would be served by the proposed TRIPS amendment. Once introduced into the TRIPS Agreement, the disclosure requirements would be a TRIPS and not a CBD obligation, notwithstanding the sought objective of mutual supportiveness between the two treaties. The amendment would not bind non-CBD parties to the provisions of the CBD, as the disclosure obligations would be acquired exclusively under and in accordance with the TRIPS Agreement. This was normal practice, particularly in the case of the

TRIPS Agreement, which had transposed several provisions contained in other international treaties into the realm of the WTO. Reference in the TRIPS Agreement to provisions taken from the Paris Convention or other WIPO treaties did not mean that non-WIPO members were obliged to comply with WIPO obligations.

65. As to whether the requirement for correction of information applied only to the pre-grant period or to the post-grant period as well, he said that the requirement would apply to both the pre- and post-grant periods as both the words "applicant" and "patentee" were used in the draft amendment. Since the failure to comply with the disclosure obligation could prevent the further processing of patent applications or result in the revocation of patents, the flexibility for submitting additional information would benefit the patent applicant or the patentee. Therefore, there should be a continuing opportunity for providing supplemental or corrected information.

66. As to with whom benefit-sharing contracts should be negotiated and the benefits be shared, he said that this was up to each WTO Member and that the draft amendment did not intend to impose a uniform approach on WTO Members.

67. In conclusion, he said that the mandate given by Ministers provided a basis for negotiations on all outstanding implementation issues, including the CBD. It did not exclude an amendment to the TRIPS Agreement as an outcome of the Doha Round.

68. The representative of Kenya supported the proposal for an amendment of the TRIPS Agreement to introduce an obligation to disclose the country of origin of genetic resources and traditional knowledge in patent applications. Such a disclosure obligation should form part of the formal requirements of patent applications. Disclosure requirements, especially as proposed by Norway, would not be burdensome to patent offices or patent applicants. It was the national competent authorities, and not patent offices, that would verify the conditions of the acquisition of genetic resources and associated traditional knowledge. The patent office would only check whether the formal requirements had been fulfilled. The patent applicant should submit the information that was best known to him.

69. The representative of Bolivia said that the amendment of the TRIPS Agreement would contribute to the success of the Doha Round. His delegation was interested in promoting the defensive protection of genetic resources and traditional knowledge and equitable distribution of the benefits derived from the use of traditional knowledge.

70. The representative of Turkey expressed his delegation's preparedness for text-based negotiations. He said that Norway's proposal included useful elements for text-based negotiations. His delegation attached equal importance to all outstanding implementation issues and expected significant movement before July 2006. He supported the introduction of a disclosure requirement into the TRIPS Agreement, but said that such an exercise should preserve the balance within the patent system. He was concerned that the cancellation of patents as a legal effect of non-compliance with the disclosure requirements might introduce uncertainties into the patent system.

71. The representative of the Philippines said that Members should preserve the legal certainty in the patent system and keep the burden on patent offices and users at a reasonable level. Nevertheless, this policy consideration had to be balanced against the equally compelling need to address the unfair exploitation of biological and genetic resources and associated traditional knowledge. This need was demonstrated by the Philippines' national experience in the last ten years. As early as 1995, the Philippines had passed "Guidelines Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources", building on which it had also passed the "Indigenous People’s Rights Act" in 1997. Thereafter, the "Traditional and Alternative Medicines Act" and the "Wildlife Resources Conservation and Protection Act" had entered into force. Despite all these laws, biopiracy

and the inequitable exploitation of genetic and biological resources had continued unabated and unchecked.

72. He said that, although most Members conceded that the TRIPS Agreement and the CBD were mutually supportive and that there was no conflict between these two Agreements, they arrived at different conclusions. From the perspective of developing Members, it was time to use the patent system to combat biopiracy. The draft amendment constituted a solid and reasonable basis for Members' collective engagement with a view to finding a resolution to the problem of biopiracy.

73. He posed the following questions to the proponents of the draft amendment: whether the proponents would consider an additional implementation period as the draft Article 29*bis* would require domestic legislative action; whether the scope of "biological resources" was broader than that of "genetic resources"; what the meanings of "reasonable inquiry" and "with reasonable grounds to know" were; whether a mere declaration by patent applicants that the providing country did not have prior informed consent and access and benefit-sharing regimes would be considered as compliance with the disclosure requirement; whether the disclosure requirements would apply retroactively to the patentee who had been granted the patent before the adoption of the amendment; and whether Members could impose fees as might be necessary to cover the cost of publishing additional information.

74. The representative of Switzerland said that, while his delegation was not a *demandeur* in the CBD issue, it saw a legitimate concern for the disclosure of source to be addressed in the patent regime, and accordingly had put forward a proposal on how this could be done at the international level in an effective and timely manner.

75. He then posed the following follow-up questions to the responses the co-sponsors had provided in document IP/C/W/470. He noted that paragraph 2 of the document stated that the fundamental conflict between the TRIPS Agreement and the CBD was the failure of the former to recognize the private intellectual property rights involved in traditional knowledge, which was owned collectively. As the TRIPS Agreement did not exclude traditional knowledge from the scope of intellectual property rights, he asked for a detailed explanation on the perceived conflict between the CBD and the TRIPS Agreement.

76. According to the definitions of "country of origin" and "source" in paragraphs 3 and 4 of the document, he asked that, for example, if a patent applicant had accessed a rubber tree in Thailand, which originated in Brazil, which country would the applicant have to declare as the country of origin: the country where the genetic resource originated immediately or the country where the genetic resource originated historically? If the historic country of origin should be declared, he said that this might result in uncertainty when it was unknown.

77. As the definition of biological resources in paragraph 5 of document IP/C/W470 encompassed not only genetic resources of plants and animals but those of human beings, he asked whether the disclosure requirements would apply to human beings as well, and if so, what the reasoning behind that would be and whether such application would create a new conflict with the provisions of the CBD, since Decision II/11 of the CBD's Conference of Parties explicitly excluded human genetic resources from the scope of application of the CBD.

78. As paragraph 6 of document IP/C/W/470 foresaw that the veracity of the document concerning prior informed consent could be challenged during opposition or revocation proceedings due to fraud or the obtaining of information from the wrong person, that the parties should seek recourse under the domestic law, and that the findings of the domestic authorities would be binding on patent offices, he sought clarification on the meanings of "parties", "domestic law" and "domestic authorities" referred to. If the "domestic authorities" meant the authority in the providing country, he

asked how it could rule on the validity of a patent granted in other countries, and how this extra-territorial application of the law of the country of origin in the patent-granting country could be justified. He further asked how the authorities in the providing country would find out about the patent granted in other countries.

79. Regarding the sanctions suggested in paragraph 13 of the document, he asked whether these sanctions would be imposed in combination or alternatively, and, if alternatively, who would decide which sanction would apply in a certain case and based on what grounds. He also asked whether the applicability of the sanctions would require fraudulent intention or negligence.

80. With regard to paragraph 16 on the implications for the WIPO PCT and PLT, he asked what these implications would be; how these implications would be introduced into the PCT and PLT, whether there was a need for amendment of the two treaties, and if so, what provisions would be affected. Regarding the integration of the disclosure requirements into the FAO International Treaty on Plant Genetic Resources for Food and Agriculture wherever applicable, he noted that the FAO Treaty neither applied the concept of prior informed consent nor the concept of the country of origin.

81. The representative of Korea said that there was little possibility of conflict between the TRIPS Agreement and the CBD and that these two instruments could be implemented in a mutually supportive manner. While recognizing the importance of preventing biopiracy and misappropriation of genetic resources, his delegation thought that introducing a new requirement into the TRIPS Agreement was not an appropriate solution. He said that case studies would help to identify problems Members faced and to reduce gaps in Members' understanding of this issue. Therefore, his delegation would continue to engage in fact-based discussion on this issue. Regarding the protection of traditional knowledge and folklore, he said that it would be desirable to follow up the discussion in the WIPO IGC in order to avoid duplication. It was also preferable to establish databases on traditional knowledge as suggested by Japan.

82. The representative of Colombia said that Members should prevent the granting of patents to inventors who had not complied with the minimum requirements for legitimate access to genetic resources and associated traditional knowledge in the country of origin. The TRIPS Agreement did not lay down any formal requirements on legitimate access, which, to some extent, promoted biopiracy. The Doha and Hong Kong Ministerial Conferences had given Members the mandate to take necessary action in order to find a solution to this issue. The appropriate solution would be to set up procedural rules in the TRIPS Agreement. He requested the Secretariat to add his delegation to the list of co-sponsors of document WT/GC/W/564/Rev.1.

83. The representative of Thailand said that biopiracy and misappropriation of genetic resources and traditional knowledge had been of great concern to his delegation. As a co-sponsor of document WT/GC/W/564/Rev.1, his delegation believed that the draft amendment would strengthen the protection of traditional knowledge. He said that, although the intellectual property system was costly, difficult and burdensome for developing countries, especially small and poor developing countries, none of them had suggested abolishing the system. Intellectual property rights should be based on fair and equitable principles, which aimed at benefiting producers, inventors, owners and consumers as a whole. The current intellectual property system did not extend protection to genetic resources and traditional knowledge, which would encourage biopiracy and hurt developing countries. The issue was thus part of the development dimension of the Doha Development Agenda. The burden resulting from the disclosure requirements was minimal, compared to that of the intellectual property system. He said that Norway's proposal showed an important convergence among Members, and that it was time for Members to move to text-based negotiations.

84. The representative of China supported text-based negotiations on the relationship between the CBD and the TRIPS Agreement because of the growing convergence among Members on this issue. He believed that document WT/GC/W/564/Rev.1 would serve as a good basis for the focused exchange of views towards a concrete solution.

85. He welcomed Norway's support of the amendment of the TRIPS Agreement to introduce a mandatory disclosure obligation in patent applications, although he had reservations on the effectiveness of sanctions outside the patent system. He encouraged Norway to clarify this point.

86. With respect to Japan's proposal, he associated himself with the position of the Indian delegation that databases did not seem to be an adequate solution in addressing the concerns that related to the misappropriation of biological resources and erroneously granted patents.

87. The representative of Japan clarified that the purpose of creating databases was to prevent erroneously granted patents. Technical issues on the establishment of such databases, such as how to ensure that databases would be used by patent offices in an appropriate way, should be further discussed in the WIPO IGC. He further clarified that the collection of information on genetic resources and traditional knowledge should respect customary law or willingness of local communities.

88. The representative of Canada said that access and benefit sharing was a broad-ranging policy issue that involved many levels of government in Canada. Some Canadian stakeholders had also become engaged, particularly in the environmental, forestry and national resources sectors. The issue of developing a consistent, coherent and effective national access and benefit-sharing policy was important for Canada. While Canada might not be a mega-diverse country, it had significant biological diversity resulting from the variety of regional climates and ecosystems and numerous and diverse aboriginal groups. Consequently, Canada was a provider of many unique genetic resources and associated traditional knowledge including plants, enzymes, soil, microbes and marine organisms. Meanwhile, she said that Canada's strong research capacity and knowledge-based economy also meant that it was a significant user of genetic resources and traditional knowledge from other parts of the world. This duality of roles, combined with a complex jurisdictional structure, created the central challenge for Canada in managing its genetic resources and traditional knowledge. Meeting this challenge was key to its ongoing national access and benefit-sharing policy development process.

89. She informed the Council that a Federal Provincial Territorial (FPT) Working Group on access and benefit sharing had been established in September 2004 and given the task of preparing a policy scoping paper and a companion national strategy for domestic engagement of governments, aboriginal peoples and stakeholders. These two documents had been prepared by the FPT Working Group and approved for release by FPT Ministers responsible for Forests, Wildlife, Endangered Species and Fisheries and Aquaculture on 5 October 2005. Since then, Canadian federal officials had been working in partnership with their provincial and territorial counterparts to, on the one hand, raise awareness about access and benefit sharing and gather information on provincial and territorial perspectives on access and benefit sharing and, on the other hand, discuss possible policy and legislative implications and options at the provincial and territorial levels, since it was these jurisdictions that had legislative responsibility in Canada for protecting biodiversity. As part of this awareness-raising and information-gathering exercise, a series of FPT Workshops on access and benefit sharing had been organized in 2005-2006. These workshops had focused on access and benefit sharing and agriculture, forest genetic resources, the science and technology agenda, and the North. The workshops had also been used as a vehicle through which to engage and inform a range of interested Canadian stakeholders on domestic and international developments regarding access and benefit sharing. Participants had included scientists, academics, some industries, aboriginal and NGO representatives. Stakeholders had also been encouraged to express their views on a wide range of issues related to access and benefit sharing, including legal consistency with existing legislation at

federal and provincial levels, existing resource management practices, existing access and benefit-sharing mechanisms in place in research institutions, *ex-situ* collections, industry, intellectual property issues and a general reflection on environmental, economic, social and legal opportunities and challenges associated with access and benefit sharing.

90. She further said that Canada had made considerable progress over the past several years in engaging stakeholders across the country. But this was not a simple task and plenty of work remained. For example, one of the biggest hurdles it had yet to get over was the complexity of the issue, the wide and sometimes contradictory range of perspectives often held within sectors or among the same stakeholders group. Her delegation remained of the view that early engagement of as many groups as possible was essential for successful access and benefit-sharing policy development and effective implementation.

91. With respect to Japan's proposal on databases, she said that her delegation was keenly interested in ensuring that the patent system was coherent, consistent and that quality patents were issued nationally and internationally. Generally, Canada was in favour of initiatives which facilitated and were relevant to the task of patent examiners engaged in the task of determining the patentability of inventions. Japan's submission had correctly identified an important problem in many developing and developed countries' patent offices. When engaged in prior art searches to determine the patentability of given inventions, some patent examiners did not have access to databases that could provide evidence that a given invention lacked either novelty or an inventive step. It was extremely difficult these days even for a skilled patent examiner to investigate all evidence of prior art in a particular field. Even after an examiner had reviewed all the available patent literature, databases of technical reports and authoritative science journals, it was still possible that he or she might have missed identifying prior art that was only documented in age-old manuscripts available in local languages, such as the "neem" and "turmeric" cases, or that was only passed on by word of mouth among generations of traditional knowledge custodians. Consequently, Japan's suggestion to consider the development of a comprehensive "one-stop-shop" database related to genetic resources and traditional knowledge that could be accessible by examiners worldwide appeared to be an idea worthy of further technical examination. Given WIPO's expertise and capacity in the area of databases, Canada considered that this technical examination would be best done in WIPO rather than the WTO or other multilateral forums. She further said that her delegation recognized that there might be significant, logistical and privacy issues involved with creating a global all-inclusive database for genetic resources and associated traditional knowledge. For that reason, Canada would support focusing first on initiatives which interlink existing and future prior art databases through common access protocols.

92. In conclusion, she said that as part of the fact-based discussion her delegation had engaged in, patent examiners' perspective on the disclosure debate was important to reach a proper understanding of the practicality and feasibility of introducing the disclosure requirements for genetic resources in the patent granting process. Canada had enquired among its own patent examiners, who had identified a number of factors that had to be addressed to fully grasp all the practical ramifications of the proposed disclosure requirements, as the overall costs and benefits of the disclosure requirements from the broader policy context should be considered. These factors included information about the originating organism in current applications and patents; prior art searches and common nomenclature; classification schemes identifying whether patents contained a claim to genetic or biological materials; and means to verify the accuracy of the source of origin of material as identified by the applicant. Her delegation would appreciate any guidance other Members could provide on these factors.

93. Another representative of Canada said that the disclosure proposal had not been the sole focus of the consultations held by the DDG. Rather, a number of different proposals had been discussed and merited further consideration. The draft amendment contained in document

WT/GC/W/564/Rev.2 made three assumptions which Canada neither agreed with, nor found to be fully reflective of the ongoing discussions. First, not all Members had accepted the case for amendment to the TRIPS Agreement as being sufficiently substantiated and thus her delegation did not agree to proceed to negotiations. Second, not all Members had agreed to overlook the fact that there was no mandate to launch negotiations on any intellectual property-related implementation issues during the Doha Round. Third, not all Members were of the view that the TRIPS Agreement and the CBD were not mutually supportive agreements. In fact, her delegation continued to be of the view that the TRIPS Agreement and the CBD were already mutually supportive, and that their objectives and principles could be reasonably implemented in a consistent fashion by countries without amending either agreement. Consequently, Canada considered the draft Article 29*bis* to be redundant.

94. The disclosure requirements would not solve the problem facing Members. She wondered whether this was the appropriate time for Members to consider moving beyond the Doha mandate. While a number of Members had suggested this as an option, there were also other options that could reasonably be considered under the umbrella of "any appropriate action". Her delegation was committed to fact-based discussions, particularly on national access and benefit-sharing systems, which would assist in finding appropriate solutions to prevent erroneously granted patents and to improve compliance with access and benefit-sharing agreements.

95. She said that the approach presented by Norway suggesting text-based negotiations went beyond the Members' mandate as they had not yet agreed on appropriate action to be taken on the CBD issue. As her delegation was currently evaluating the various disclosure proposals, it could learn much about practicality, feasibility and costs of the introduction of the disclosure requirements from other countries that had implemented it in their national legislation, such as Germany, Belgium, Sweden, Denmark, Norway, Brazil and India. A preliminary observation of these initiatives indicated that the subject-matter to be disclosed varied. The expression privileged in international discussions was "genetic resources", but "genetic material", "biological resources" as well as "genetic or biological heritage" were also referred to. She had expressed her delegation's concerns over the costs and benefits to patent offices, the assessment of compliance, the trigger for such disclosure, and the checkpoints for access and benefit sharing. She had noted that the disclosure requirement was one of many potential tools with which Members could address the principles and aims of emerging access and benefit-sharing policies at international and national levels.

96. The representative of Australia said that Australia was a mega-diverse country with possibly the world's highest level of endemic genetic resources, much of which had yet to be characterized. Australia also had an indigenous community which had accumulated traditional knowledge over thousands of years of interaction with the Australian continent. At the same time, Australia was a developed country with a burgeoning biotechnology industry and a large agriculture sector, as well as large agricultural and environmental research sectors which were reliant on access to genetic resources. For these reasons, Australia had a strong interest in facilitating research, encouraging innovation and capturing the benefits from that innovation, ensuring that Australia was able to exercise appropriate control over these resources and ensuring that the benefits from such access were equitably shared. To do this successfully, the rights of all stakeholders had to be balanced so that research and innovation prospered and so that owners of genetic resources and traditional knowledge were respected and obtained appropriate benefits from any outcomes.

97. These were precisely the factors that had influenced the development of Australia's own access and benefit-sharing regime under the Environment Protection and Biodiversity Conservation Act of 1999. The Regulations under the Act had come into force only on 1 December 2005 and were based on the Bonn Guidelines. The Regulations established a contract-based permit system to manage the access and distribution of benefits derived from native genetic and biochemical resources. In a nutshell, to gain access to the material, one needed to obtain a permit from the Minister for the

Environment or his delegate and to provide evidence of a benefit-sharing agreement with the owner or manager of the biological resource. The legislation clearly set out the criteria that needed to be met.

98. In addition, Australia was in the process of developing a model contract as a guide to assist the parties when developing a benefit-sharing agreement. It would not be mandatory, but aimed to provide assistance and incorporate best practice examples from similar agreements worldwide. The model contract was designed to address one of the main critiques of the contract-based system, i.e. that indigenous communities and other owners of genetic resources and traditional knowledge were not in a position to negotiate effectively. Overall, the purpose of this legislation was to give investors in the industry confidence and security when committing to large and sustained investment in research and development whilst also ensuring that Australia's genetic resources were used in an environmentally sustainable manner, on mutually agreed terms with prior informed consent and with an equitable return for Australia.

99. There was not necessarily a relationship between Australia's access and benefit-sharing regime and its intellectual property or patent regimes. Parties could include terms in the contract that stipulated that if the resources were commercialized including through a patent, certain benefits would flow. This recognized that many uses could be made of genetic resources and traditional knowledge outside the patent system and that biopiracy could occur outside the patent system. The issue of biopiracy, therefore, should be addressed at the access phase. As the contract system was still new, a number of licences were under negotiation, but none had been completed yet. It was still too early to assess the system, but it was going well in terms of delivering real benefits to genetic resource and traditional knowledge owners.

100. He said that his delegation had proposed focusing Members' attention on access and benefit-sharing regimes. It was interested in hearing from other Members the details of the practical problems that they had experienced in implementing and operating their regimes. Referring to the statements made by the Philippines that its national access and benefit-sharing regime had not worked adequately in the prevention of biopiracy, and therefore it supported using the patent system as a solution to biopiracy, he said that there were many possible reasons for this unfortunate experience. It was vital to examine the nature of the problems experienced by Members, the reasons why they had occurred and what was the most appropriate solution.

101. Another representative of Australia said that it remained unclear to her delegation how the disclosure requirement itself would have prevented the granting of patents in the turmeric and other cases that had been discussed in the TRIPS Council. The argument for the disclosure requirements seemed to be that patent applicants would be less likely to lie when confronted with an explicit disclosure requirement or that an explicit disclosure requirement would provide patent examiners with additional clues in determining prior art. However, her delegation believed that such arguments would not justify an amendment of the TRIPS Agreement or other international patent treaties. Instead, her delegation saw value in pursuing more practical ways to prevent the granting of erroneous patents, such as the database system proposed by Japan. In addition, she wondered whether it was appropriate for the TRIPS Agreement to enforce the objectives of prior informed consent and benefit sharing provided by other international agreements. She expressed her concern over the uncertainty that the disclosure requirement would engender in the patent system, given that many Members had not yet established access and benefit-sharing regimes. Invalidating patents because of non-compliance with access and benefit-sharing regimes that might not exist or were unclear would put at risk the integrity of the patent system with implications for the ability to share benefits. She also expressed concern over the burden imposed on patent offices by the disclosure requirements.

102. In conclusion, she reiterated her delegation's approach to this issue: first, a clear examination of the problem, second, development of options for solutions, and third, negotiations. Accordingly, he believed that it was premature and inappropriate to move to negotiations at this stage. Members

could not amend the TRIPS Agreement unless they had identified the problem with national access and benefit-sharing regimes. Therefore, Members should start with technical discussion to identify the problem, and then develop proposals for options for an appropriate solution, and then move to negotiations on those options. Many safeguards and balances had been built into the patent system, and when Members considered a new measure, they should ensure that the measure was capable of meeting its objectives while preventing adverse consequences.

103. The representative of the United States said that her delegation was one of several Members that did not see a conflict between the TRIPS Agreement and the CBD, and considered that these two agreements could and should be implemented in a mutually supportive manner, and that no amendment to the TRIPS Agreement was needed or warranted. Nonetheless, she recognized that there remained a wide divergence of views among Members on this issue, including advocacy of a variety of approaches. In light of this, it was premature to engage in a text-based discussion. Document WT/GC/W/564/Rev.1 might help to elaborate the conceptual position of its co-sponsors, but it could not be a basis for the Council's future work. The future work should continue with fact-based discussion, which should include examination of existing access and benefit-sharing regimes, as it appeared to be directly related to perceptions of what constituted "misappropriation". It would facilitate progress in this area and would continue to clarify points of disagreement while reducing differences among Members.

104. The US proposal on national access and benefit-sharing systems was directed to the goal of providing appropriate access and equitable benefit sharing. With respect to mistakenly granted patents, the proposals on use of searchable organized databases, disclosure of information material to patentability, and use of post-grant opposition and/or re-examination procedures could directly achieve this objective. Her delegation had closely reviewed the arguments made by the proponents of the disclosure requirements and continued to believe that the disclosure requirements were not an appropriate solution to meet the concerns raised. She further said that there seemed to be universal recognition in the TRIPS Council that at least a national access and benefit-sharing regime was necessary for the proper running of the benefit-sharing aspects of any such system. Thus, it was clear that in order to achieve the objectives of prior informed consent and equitable benefit sharing, national laws outside the patent system that directly and effectively regulated such conduct were critical. Her delegation had long observed that concerns about misappropriation arose more broadly than in the context of products under the patent protection. Many countries had only recently enacted or were in the process of enacting national access and benefit-sharing systems. Focusing on mechanisms to strengthen national regimes outside the patent system in order to address all instances of commercialization of misappropriated resources and/or traditional knowledge that needed to be addressed regardless of whether these instances involve patenting or not, led to a more comprehensive and appropriate solution to the purported problems and issues. It was unclear in the arguments of the proponents of the disclosure requirements why national access and benefit-sharing systems were insufficient with respect to misappropriation that was followed by the filing of a patent application, although it could sufficiently handle all other forms of misappropriation which potentially had even greater commercial consequences.

105. She said that in order to better understand perceived instances of misappropriation, the TRIPS Council should continue its consideration of fact-based examples and examine national experiences regarding access and benefit-sharing systems to identify perceived problems with or gaps in these existing systems. It was not clear how the mere fact that a pending patent application or a granted patent that referred to genetic resources or claimed an invention that might have some relation to genetic resources could lead to a conclusion that the genetic resource or traditional knowledge at issue had been obtained illegally, irregularly or questionably, especially given the availability of such resources commercially. Many of the resources cited by some Members in the course of discussions were grown in many countries throughout the world and further many such resources had been exported and sold as raw materials for direct consumption or industrial processing with a view to

immediate economic benefits. Whether these exports were subject to national access and benefit-sharing regimes in Members needed to be explored.

106. She said that a cursory review of several of the patents listed in recent submissions as evidence of biopiracy or misappropriation revealed that the inventors of these patents had in fact disclosed the source and/or origin of the genetic resources related to the inventions. Given that fact, it was clear that the proposed new disclosure requirements, in and of themselves, would not attain the purported goals. Rather than advocate burdensome remedies that would not address underlying problems, Members should enquire as to how existing access and benefit-sharing systems dealt with genetic resources, for example, whether, if genetic resources were exported as raw material for direct consumption or industrial processing or otherwise traded as commodities, this might impact upon perceptions of illegal and otherwise wrongful behaviour. In her view, the disclosure requirements would not address large volumes of resources that might be exported from countries apparently exempted or unregulated by national access and benefit-sharing systems that, after travelling through the normal channels of commerce might eventually be used as starting materials for research and/or innovation. In the absence of evidence to support the assertion that the disclosure requirements would achieve their intended outcomes, it was problematic for Members to consider such requirements in light of the disincentives they were likely to have on innovation. She further said that the patent system was a critical incentive mechanism for promoting research and development of new inventions of legally obtained or accessed material. This was what ultimately resulted in new inventions that enhanced living conditions, including life saving medicines, higher crop yields and better treatments for disease. All Members had a stake in encouraging and not discouraging this process.

107. She said that national contract-based systems could be adequately enforced outside the patent system. Such contract-based systems could be part of civil and criminal codes specifically designed to enforce access and benefit-sharing laws. Such systems could be international in character and could contain, *inter alia*, choice of forum, choice of law, or international arbitration provisions relevant to cross boundary dispute or enforcement issues. Such systems were widely used in international business transactions and could and did function to enforce the mutually agreed terms between parties. Nevertheless, her delegation was still open to further discussion on the enforcement issue.

108. She said that the disclosure requirements were primarily aimed at preventing mistakenly granted patents. However, due to the tenuous relationship between source and/or country of origin to issues relating to prior art and inventorship, it was not likely that the disclosure requirements would provide any helpful information to patent examiners. The problems cited by Peru in its recent document, including limited information in the English language in certain patent databases, difficulty in finding prior art because of lack of systematization of information and in finding documents relating to particular customs, were illustrative of broader concerns. The disclosure requirements would have little, if any, bearing on how to alter the situation cited by Peru.

109. She said that her delegation fully supported the Japanese proposal's goal of improving prior art search systems and that it had made several proposals directly related to this goal, including use of organized databases of prior art. She found the detailed analysis provided by Japan on the turmeric and neem cases consistent with her delegation's analysis of these cases, which led to the conclusion that the disclosure requirements could not fulfil its purported objective. She supported further consideration of Japan's proposal, including the use of languages, assessment and identification of compilation of the database and the notion of a "one-stop-shop" database. She said that the ongoing work in WIPO could continue to inform the discussion in the TRIPS Council in this regard.

110. She said that her delegation would continue to study other examples that had been cited to support the premise that disclosure of source and origin of country would be effective in preventing mistakenly granted patents. The premise appeared to be inconsistent with the fact-based discussions

held to date. The proponents of the disclosure requirements appeared to assume that what was known about a genetic resource prior to research and development was what led the inventor to the patented invention. Such was not the case in many, if not most, circumstances. Many inventions were the culmination of numerous researchers seeking a solution to a problem or the result of an unexpected finding while seeking information on an unrelated experiment. For example, it had taken more than thirty years with hundreds of millions of dollars of private sector investment to develop the anti-cancer medication Taxol, which had originally been isolated from the Pacific Yew in Washington State in the United States. This illustrated the real and costly efforts undertaken to develop a biological resource into a commercially successful product, and the risks involved in undertaking such research and development. Many medicines that were developed from plant and animal extracts were the result of arduous research efforts, unexpected research results or trial and error experimentation. The patent system was designed as an incentive for innovators to undertake such intensive and expensive research and development by rewarding them an exclusive right to exclude others from using the invention for a limited time. Members should be wary of potentially upsetting this system by introducing new patent disclosure requirements.

111. She noted that the proponents of the disclosure requirements had a presumption, without empirical evidence, that an invention related to a genetic resource was automatically based upon illegal access or misappropriation. However, she said that many genetic resources were indeed commercially sold, legally obtained and independently researched and developed into inventions. She further said that the recent fact-based discussion had helped to identify some apparent common ground among Members, including that national access and benefit-sharing systems were essential elements of any solution and further that Members appeared to share the concern over how to improve prior art search mechanisms for patent offices around the world with the objective of preventing mistakenly granted patents. She reiterated that her delegation would continue to engage in the fact-based discussion, including the analysis of the issues, such as perceptions of illegality of access, genetic resources traded as commodities, the relationship of traded genetic resources to national access and benefit-sharing regimes in place, as well as the relationship of traded genetic resources to starting materials that might be used for research and innovative purposes.

112. Another representative of the United States responded to three questions posed to his delegation earlier by India. As to a question about whether the civil and criminal penalties as proposed by the United States were envisioned to apply to acts in foreign countries, and if so, how such laws could be enforced internationally, he said that contract-based access and benefit-sharing systems could be adequately enforced outside patent laws through civil and criminal laws. Such systems could be international in character and were easily adaptable. Compliance with such systems would be facilitated by the establishment of clear, transparent, contract-based national access and benefit-sharing regimes. While a few individuals could ignore the legal requirements, as they might ignore other laws or regulations, the case had not been made for why a contract-based system would not be effective, particularly when compared to the alternative proposal for the disclosure requirements, which had speculative benefits at best, yet would be likely to result in negative effects on the patent system and benefit sharing. He recalled that his delegation had described in detail its national experiences with the access regimes in the US national parks and national cancer institutes.

113. Replying to another question on the further work on international recognition of access and benefit-sharing systems, he said that his delegation had not requested such further work *per se*, but instead had suggested further study of national access and benefit-sharing systems, including identification of perceived problems or gaps in existing systems in order to better understand concerns raised. Such study would be helpful in understanding perceived instances of misappropriation. Further questions had been raised regarding exports of genetic resources as raw material or otherwise as commodities that had been legally obtained. He said that further study on these issues would help to clarify concerns and find appropriate resolution to these concerns.

114. Responding to a further question as to what would be the implications for patent systems if the disclosure requirements had been limited to a patent office simply collecting and publishing evidence of prior informed consent and benefit sharing and not examining or adjudicating such evidence, he said that the disclosure requirements, including those requiring evidence of prior informed consent and equitable benefit sharing, would have significant negative impacts on the patent system. These requirements would create, among other effects, a cloud of legal uncertainty over patent rights, thereby inhibiting research and development and diminishing or eliminating potential benefit sharing. He recognized that, according to some proposals for disclosure requirements, patent offices might not have to examine or adjudicate evidence of prior informed consent or benefit sharing. While this might lessen the burden on patent offices with respect to the task of examining foreign access and benefit-sharing systems which patent examiners would be ill equipped to assess, a cloud would nonetheless remain over all granted patents for which this issue might be relevant. These disclosure requirements would provide an additional avenue to litigation and other uncertainties that would undermine the role of the patent system, even where good faith attempts to comply had been made. These potential litigation challenges impacted negatively upon research and development and innovation by creating uncertainty over a patent, which was a clear necessity in attracting investment for research and development. Thus, such disclosure requirements not only had the potential effect of undermining the technological development incentives of the patent system, but would also have a negative effect on any possible benefit sharing. However, contract-based mechanisms could ensure appropriate access by ensuring prior informed consent and equitable benefit sharing without upsetting the incentives critical in the patent system that promote research and development and innovation. In addition, he said that Members could not make progress on a solution with respect to the concern over misappropriation without looking at national access and benefit-sharing regimes, which went directly to the heart of the relationship between the TRIPS Agreement and the CBD.

115. The representative of New Zealand said that New Zealand did not have a dedicated national access and benefit-sharing regime. However, it had established several laws to regulate access to, and use of, genetic resources. There were two formal access regimes in New Zealand: the Department of Conservation Concessions Regime and the Ministry of Fisheries Fishing Permit or Special Permit Regime. In addition, access to genetic resources located on private land was subject to the landowner's consent according to common law unless the resource in question had been specifically claimed by the Crown through legislation, such as the Wildlife Act. Failure to obtain the landowner's consent would be considered theft. As the agreement with the private landowner might be informal and/or ad hoc, in many cases there might be no evidence of prior informed consent and benefit sharing. Under the Department of Conservation Concessions Regime, an application form must be submitted to the Department for the taking of resources, including genetic resources, for research purposes. A fishing permit or a special permit was required to access aquatic life in New Zealand waters. The access requirement would differ depending on the source. The law required consent for access to genetic resources, but it was not clear to bioprospectors what requirements they should fulfil in certain circumstances. The consultation with private companies indicated that the absence of an access and benefit-sharing regime was a disincentive to bioprospecting. He said that national access and benefit-sharing regimes must be the primary means for addressing concerns over access to genetic resources. Therefore, New Zealand had been making efforts domestically, such as national capacity building to allow for the effective engagement of indigenous groups in the debate on this issue, exchange of information between officials and indigenous groups about their concerns about misuse of traditional knowledge and benefits for indigenous economic development.

116. He said that the introduction of a new disclosure requirement would increase complexity without clear benefits. His delegation continued to have concerns about the suitability and practicality of the disclosure requirements in the absence of widespread access and benefit-sharing regimes at the national level. His delegation was interested in hearing other Members' national experiences in order to identify problems and find appropriate solutions.

117. The representative of the European Communities, commenting on the communication submitted by the group of developing countries (IP/C/W/470), said that his delegation could go along with the distinction between "country of origin" and "source of the genetic resource" made in that document. Article 2 of the CBD defined "country of origin" as the country which possessed those genetic resources in *in situ* conditions, that is conditions where genetic resources existed within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they had developed their distinctive properties. The term "source" referred to any source from which the applicant had acquired the genetic resource other than the country of origin, such as a research centre, a gene bank or a botanical garden. However, while the co-sponsors of document IP/C/W/470 suggested that the applicant disclose both the country of origin and the source, his delegation believed that the applicant should disclose the country of origin if he was aware of it without being obliged to undertake further research. If the country of origin was unknown, the applicant should disclose the source of the genetic resource to which the inventor had had physical access and which was still known to him.

118. Regarding the incorporation of traditional knowledge in the definition of country of origin, he said that as traditional knowledge was not defined in the CBD and as there was no commonly agreed meaning of it, a further in-depth discussion on this issue was needed.

119. Regarding the use of the terms "biological resources" and "biological material" instead of "genetic resources", he did not agree with the statement that these terms would be interchangeable. He said that Article 15.7 of the CBD laid down that access and benefit-sharing objectives must be met with regard to genetic resources. Article 2 of the CBD defined genetic resources as genetic material of actual or potential value. Article 15 of the CBD did not apply to biological resources. "Biological resources" was broader than "genetic resources" and was defined to include genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. Broadening the scope to biological resources would mean that any component of ecosystems with actual or potential value could be subject to the disclosure requirements. This would introduce further uncertainty to both patent applicants and patent offices. Therefore, he suggested retaining the term "genetic resources" as referred to in Article 15.7 of the CBD.

120. Regarding the obligation to disclose evidence of prior informed consent and benefit sharing, he said that many countries had not yet adopted legislation on access and benefit sharing and were therefore not in a position to deliver certificates. Even in some countries where such legislation existed, difficulties with implementing the legislation had been reported. Those who were the most advanced in domestic policy-making should share their experience with other Members. The patent system should not be used to verify compliance with national access and benefit-sharing regimes.

121. With respect to document IP/C/W/469, submitted by the United States, he agreed that national contract-based access and benefit-sharing systems were essential elements of any solution. He also agreed that remedies to prevent erroneously granted patents should include the use of organized databases, information material to patentability and the use of post-grant opposition or re-examination systems alternatives to litigation. However, his delegation considered that the requirement of disclosure of the country of origin or source of the genetic resource used in an invention would be helpful to patent offices, provided it was properly calibrated. It would help to establish novelty by making searches focused and thus prevent the misappropriation of genetic resources and related traditional knowledge. The introduction of the disclosure requirement was not, and should not be, the only solution to fulfil the CBD objectives, but it could contribute to the other solutions, such as contractual arrangements. He agreed to continue considering national experiences regarding access and benefit-sharing systems, identifying perceived problems or gaps with these existing systems, and proceeding to discuss how these problems could be addressed. However, he said that this should not prevent Members from continuing discussions on the disclosure requirement.

122. Regarding document IP/C/W/473 from Norway, he noted several similarities between it and the EC proposal to WIPO, including that the disclosure obligation should apply to all patent applications at international, regional and national levels; that the legal effect of non-compliance with the obligation should be outside the patent system; and that a simple notification system should be introduced under which patent offices would send declarations of origin they received to the CBD Clearing-House Mechanism. However, the Norwegian proposal deviated from the EC proposal on several points, including that the disclosure obligation should apply to all traditional knowledge and not only to traditional knowledge which was directly linked to genetic resources; that the scope of the disclosure requirement should not be limited to source and/or origin of genetic resources but should also include the information on prior informed consent; and that the TRIPS Agreement should be amended to incorporate such requirements.

123. Regarding document IP/C/W/472 from Japan, he said that the relevant work undertaken in WIPO should be taken into account, where appropriate, by the TRIPS Council, in order to avoid the duplication of efforts.

124. The representative of the Philippines expressed his delegation's willingness to share its national experience with other Members. However, he doubted the usefulness of discussion of Members' national experience, considering the time constraints. He said that because of the absence of the disclosure requirements in most Members' patent systems, Members could not find a comparative benchmark to test the effectiveness of the disclosure requirements. While looking at a great diversity of Members' national experiences, Members should examine whether the disclosure requirements could be either alternatives or complements to national access and benefit-sharing regimes. Text-based negotiations would provide Members with an opportunity to discuss the practical, legal and policy implications of the disclosure requirements. He said that, as indicated by the delegations of Brazil and India, the disclosure requirements would be only an additional formal requirement, which would not constitute a disincentive to innovation.

125. The representative of India said that it had taken the Indian Government seven years to set out its national legislation on access and benefit sharing. The legislation might function well at home, but could not solve problem of transboundary use of genetic resources and traditional knowledge. Hence, his delegation had put forward the disclosure proposal in the TRIPS Council, from which national access and benefit-sharing system could benefit. He said that Australia's national experience showed that a contract-based solution might not work, given the unequal negotiating power of the aboriginal communities and bioprospectors. Also, the voluntary nature of the contract itself determined that it would not work effectively. He said that the aim of the disclosure proposal was not to cover the entirety of the range of systems presented by New Zealand. Instead, it only proposed a solution in the patent system.

126. He further said that the discussion in the TRIPS Council had shown increasing support for an amendment to the TRIPS Agreement in order to insert the minimally burdensome disclosure requirements. Concerns and questions raised by Members had been largely addressed. Even those who had expressed opposition to the amendment had shown that they had benefit-sharing systems domestically, but some of them admitted to possible inequity between the mutually agreeing parties in those access and benefit-sharing systems. For this group, the next step could be the consideration of the draft text with a view to using the proposed amendment to address some of these equity issues. The outcome of these negotiations would be a key component in the fulfilment of the development dimension of the Doha Round.

127. The representative of Brazil said that defining prior art might help to improve patent quality, but did not address the issue of the relationship between the TRIPS Agreement and the CBD. This was because the improvement of prior art searches would not achieve a supportiveness of the CBD objectives. While it was interesting to discuss the patent quality and possible changes to prior art

searches, it would not bring a solution to the misappropriation of biological resources on an international scale.

128. Regarding the legality of use of genetic resources mentioned by the United States, he said that this issue had not been addressed in the draft amendment. The disclosure requirements would provide a tool for monitoring and tracking information regarding the use of biological material and traditional knowledge. If there was misappropriation of biological resources and traditional knowledge, the patent application would not be further processed or the granted patent might be revoked. Patent offices would not judge the legality of the purchase of or access to a particular biological resource. The disclosure requirement had no bearing on exports of biological resources.

129. Regarding the national contract-based approach, he said that a number of Members would be required to adjust their civil or criminal codes, which would not provide an incentive to innovation but would facilitate biopiracy on an international scale because of the great diversity of national regimes. The amendment would improve incentives to innovation. National experiences, although interesting, did not have a direct bearing on Members' mandate to examine the relationship between the TRIPS Agreement and the CBD. Moreover, negotiations in the WTO were not usually based on a fact-based examination of national experiences. He recalled that the TRIPS negotiations had not taken into account, nor been conditioned upon, any examination of national experiences. Therefore, Members should not limit their work to fact-based discussion or divert their attention to national experiences. The TRIPS Council was a forum for Members to negotiate internationally binding treaties.

130. In conclusion, he said that as a great number of Members had made substantive comments on the proposal for amendment of the TRIPS Agreement, the time was ripe to move towards text-based negotiations.

131. The representative of Australia could not share the conclusion reached by India that the Australian model contract was not effective in addressing the misappropriation of genetic resources and traditional knowledge. He said that Australia had long experience in relation to access and benefit sharing on copyright issues, such as the collective management of copyright in relation to indigenous images. The images created by Australia's indigenous population were popular both in Australia and overseas. Initially, Australia had encountered the problem of not only commercial misuse and inequitable distribution of rewards stemming from the commercial use of such images, but also of a deeply religious and spiritual sentiment of abuse of the indigenous communities as a result of unregulated access to the images. In that context, Australia had worked very closely with a range of stakeholders, including primarily the indigenous communities. Based on international best practices, Australia had developed a range of model contracts, which had been successful in empowering indigenous control and access and benefit sharing in relation to copyright issues, and, in particular control over indigenous images. He agreed with the delegation of India that the model contract alone might not be enough to address the problem. Hence, Australia had invested heavily in a wide ranging education programme with the indigenous communities to make them aware of their rights and the dangers of uncontrolled access to their images. This had led to a dramatic increase in the confidence of these indigenous groups in dealing with people who wished to use their images. As a result, Australia's indigenous groups were quite competent negotiators, and drove a hard bargain. In relation to copyright management, there was a good framework for identifying what appropriate bargains might look like. The indigenous groups were confident and aware of the issues compared to the former situation where often they had refused to negotiate at all. They objected to broader distribution of these images on spiritual or religious grounds as they were inappropriate for such purposes. This had been a good practical solution to the access and benefit sharing issue. He further said that the exchange of national experiences might help Members introduce good model access and benefit-sharing regimes.

132. The representative of UNCTAD said that in response to a request made by the CBD Secretariat to UNCTAD to examine issues related to disclosure of origin requirements in intellectual property applications, UNCTAD had commissioned Joshua Sarnoff and Carlos Correa to prepare a paper entitled "Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications". He indicated that the views expressed in the paper were those of the authors and did not necessarily reflect those of the UNCTAD Secretariat. The study identified a need for an international system of mandatory disclosure of origin requirements and set out the possible features of such a system. It addressed questions of terminology and scope, before discussing issues including choices for model provisions on disclosure requirements and the choice of treaty regime in which to adopt requirements. Options relating to substantive and procedural triggers for disclosure requirements were examined, and the authors also considered incentives for the enforcement of such obligations. In addition, the paper looked at practical issues related to the enforcement of disclosure requirements within existing treaties, and analyzed intellectual property law issues raised by the use of international certificates of origin. The study's authors argued that a system of mandatory disclosure of origin requirements could be an effective way to contribute to goals of deterring the misappropriation of genetic resources, strengthening the intellectual property system and promoting the fair sharing of benefits derived from the use of genetic resources and associated traditional knowledge.

133. The representative of India said that the paper introduced by UNCTAD was useful as it contained material on the definition and terminology issues which Members would eventually need when they would develop a text for the amendment to the TRIPS Agreement.

134. The representative of the United States said that the paper represented the opinion of the two authors who had long been known as supporters of the disclosure requirements. However, Members were still far from any consensus on this issue and his delegation was of the view that the disclosure requirements were not an appropriate solution. He indicated that the paper could be an informative document for delegations, but must be understood in its appropriate context. He hoped that UNCTAD would commission studies on alternatives to the disclosure requirements, which would be helpful for Members in their future discussion.

135. The Council took note of the statements made under these three agenda items and agreed to revert to them at its next meeting.

F. NON-VIOLATION AND SITUATION COMPLAINTS

136. The Chairman recalled that paragraph 45 of the Hong Kong Ministerial Declaration directed the TRIPS Council to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to its next Session. It was agreed that, in the meantime, Members would not initiate such complaints under the TRIPS Agreement.

137. He further recalled that, at its meeting in March 2006, the Council had agreed to keep this item on the agenda as a regular item so as to allow Members who had new thinking to share it, and also enable the Council to consider improved ways of organizing its work on this matter.

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

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

139. No statements were made under this agenda item.

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

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

141. The Chairman recalled that Article 24.2 provided that the Council should keep under review the application of the provisions of the GI Section of the Agreement. As agreed by the Council at its meeting in March 2006, he had held consultations on how the Council should organize its future work. In the light of these consultations, it seemed that Members still needed more time to reflect on the matter. He therefore suggested that he hold further consultations on the matter and that the Council revert to this matter at its next meeting.

142. In addition to recording the discussions in the formal session of the Council, the minutes below on this item also reflect, as agreed to by the Council, additional points made by certain delegations at an informal meeting of the Council held on 14 July 2006.

143. The representative of the European Communities said that his delegation attached great importance to this issue and felt that there was a need to move forward on this matter in order to find a more focused and structured way to continue the work that this Council had already started. In previous discussions, several ideas had been floated on how to carry this work forward, including his delegation's suggestion for an options paper. He was open to examining any proposal on how to structure future work and considered that two elements were essential for doing so. First, one should concentrate on the examination of the application of the TRIPS provisions on geographical indications, as stated in Article 24.2, and not on implementing legislation. A substantial exercise had already been carried out with regard to national implementing legislation, which should not be replicated under this item. Such a review was not foreseen specifically for geographical indications and it would be extremely resource intensive, and was not carried out in respect of any other section of the Agreement. Secondly, one should take advantage to the maximum extent possible of the work done so far, in particular of the replies to the checklist of questions and the Secretariat's summary paper (IP/C/W/253/Rev.1). The summary paper already contained many of the elements mentioned by delegations, such as how Members applied their obligations and a list of practical examples of GI protection.

144. Any agenda for future work could, for example, be based on the different sections of the summary paper: overview of the means of protection available; definition and criteria for recognition; procedures for recognition; eligible authorized users and monitoring; protection against improper use; and enforcement and relationship with trademarks. Such an approach would allow Members to comment on the summary paper, and also provide any necessary updates. It would be helpful to draw general lessons from Members' replies to the checklist in a structured manner, making sure that the approach was of a general nature and not focused on the way Members had implemented their specific obligations on geographical indications. This would allow Members to benefit from the wealth of information that had been submitted so far by Members and processed by the Secretariat. All Members could gain from exchanging views and information on their experience in protecting geographical indications. In particular, many Members that had only relatively recently established TRIPS-compliant GI protection systems would benefit from it.

145. He suggested that an annotated agenda, based on the headings and the contents of document IP/C/W/253/Rev.1, be circulated by the Chair, so as to allow Members to continue with this process.

146. The representative of the United States said that, during past discussions under this item, his delegation had indicated its belief that the Council should follow the proposal made by Australia to walk through the provisions on geographical indications paragraph by paragraph. His delegation was particularly interested to see how countries had ensured that protection was available for nationals of other Members to protect their geographical indications. A closer look at the details of domestic implementation of GI protection based on the "walk through" of the provisions would provide not

only the best, but also the necessary platform for ascertaining the benefits of protection and the implementation problems countries had faced. He expressed an interest in attending any consultations that the Chair might choose to have on this matter.

147. The representative of Australia, echoing the comments made by the United States, referred to document IP/C/W/211, submitted by his delegation in 2000. Australia's preferred approach continued to be to go through all of the provisions of the Agreement relating to geographical indications.

148. The representative of Switzerland said that his delegation attached great importance to this agenda item and thus to a structured and focused review under it. The discussion should be structured according to the headings of the updated summary note of the Secretariat (document IP/C/W/253/Rev.1) on the information provided by Members in response to the checklist on the way they had provided protection for geographical indications at the national level. The question of which of these headings would be discussed in the next meeting should be determined by the Council or by the Chair in advance of that meeting and confirmed in a circular letter by the Secretariat so that Members would be able to prepare their interventions or submissions effectively in a timely manner. Members that had not yet provided information in response to the Secretariat's checklist should be encouraged to do so. The more information that was available, the more meaningful this review would be.

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

I. TECHNICAL COOPERATION AND CAPACITY BUILDING

(i) Annual Updates on Technical Cooperation Activities

150. Turning to the arrangements for the annual review of technical cooperation, the Chairman recalled that the Council had traditionally undertaken such a review each autumn. He therefore suggested that the Council hold its annual review of technical cooperation at its next meeting scheduled for 25-26 October. Accordingly, 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. Furthermore, he suggested that the Council might request that this information be made available by 29 September, i.e. approximately three weeks prior to the Council's next meeting, in order to allow its timely circulation before that meeting.

151. The Council so agreed.

(ii) Other matters

152. The representative of the Secretariat said that, while the Secretariat would report more fully on its TRIPS-related technical cooperation activities to the next session of the Council, he wished to take this opportunity to inform the Council in regard to the follow-up by the Secretariat to the provisions on enhanced technical cooperation in the TRIPS Council Decision of 29 November 2005 on the extension of the transition period for least-developed country Members. He recalled that paragraph 2 of the Decision provided that "with a view to facilitating targeted technical and financial cooperation programmes, all the least-developed country Members will provide to the Council for TRIPS, preferably by the 1 January 2008, as much information as possible on their individual priority needs for technical and financial cooperation in order to assist them taking steps necessary to

implement the TRIPS Agreement". Paragraph 3 of the Decision concerned technical and financial cooperation to be provided by developed country Members and paragraph 4 technical assistance and capacity building by the WTO in cooperation with WIPO and other international organizations. Paragraph 4 provided that "[i]n order to assist least-developed country Members to draw up the information to be presented in accordance with paragraph 2, and with a view to making technical assistance and capacity building as effective an operation as possible, the WTO shall seek to enhance its cooperation with the World Intellectual Property Organization and with other relevant international organizations".

153. The Secretariat had received requests from ten least-developed countries for national workshops this year, which it welcomed. Two of these had already been undertaken and the remaining eight were scheduled for the second half of the year. The Secretariat was suggesting to each of these countries that the workshops should include components geared towards the type of needs assessment foreseen in paragraph 2 of the Decision, and this could include a separate meeting with key officials for this purpose.

154. He also informed the Council that, in response to paragraph 4 of the Decision and based on the WIPO-WTO Cooperation Agreement of 1995 and also the Joint Initiative on Technical Cooperation in Favour of LDCs by the Directors-General of the two Organizations, it was envisaged that the eight remaining workshops this year would either be organized jointly with WIPO or that WIPO would provide a resource person. He expressed his appreciation of the contribution that WIPO was willing to make in this regard.

155. The WTO Secretariat had reached its capacity limits as far as workshops for LDCs in 2006 were concerned. However, he urged interested LDCs to include a workshop in their technical cooperation requests for 2007 and to give the Secretariat as much notice as possible in this regard in the light of the provisions of the Decision. WIPO had also agreed to support these activities next year and had further indicated that it would take into account the needs assessments foreseen in paragraph 2 of the Decision in its own technical cooperation activities in favour of LDCs wherever feasible.

156. The Council took note of the information provided.

J. ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS – COMMUNICATION FROM THE EUROPEAN COMMUNITIES

157. The Chairman said that this item had been put on the Council's proposed agenda at the request of the delegation of the European Communities, dated 10 May 2006. He recalled that the Council had discussed this topic at its three last meetings on the basis of three communications from the European Communities (IP/C/W/448, 468 and 471). At the last meeting, some delegations had indicated that they wished to comment on these papers, in particular the latest one focusing on border measures that had been made available just prior to that meeting.

158. The representative of the European Communities said that his delegation had launched a debate in the TRIPS Council more than a year ago on the worrying status of IP enforcement worldwide and the negative consequences of piracy and counterfeiting, including for the health and safety of citizens and the economic viability of companies and right holders. Several Members had supported this initiative, expressing similar concerns and the willingness to continue the discussion in the Council. The issue was also being debated in other forums such as G8, Interpol, the OECD, the WCO, WIPO and the WHO. However, these international organizations lacked a clear, coherent and effective set of rules as contained in Part 3 of the TRIPS Agreement.

159. At the Council's last meeting, his delegation had introduced a communication which was designed to initiate a debate on the use of customs measures specifically as a means to fight the global traffic of IPR infringing goods. Customs had a prime role to play in stopping the international movement of fake goods, as they were responsible for about 70% of all seizures of counterfeit goods globally. Several delegations had indicated their desire to comment on this issue. His delegation had therefore requested that the item be put on the agenda again. Rather than being negative or consisting of finger-pointing, he wished that the discussions could be positive and trigger an exchange of views on best practices.

160. He reiterated the request he had made at the Council's previous meeting that the Secretariat be invited to prepare a synopsis of Members' contributions to the Checklist of Issues on Enforcement (IP/C/5). A summary of these responses would constitute a useful element for future discussions.

161. The representative of China said that his delegation had already made detailed comments on the EC communications at the Council's last meeting. For the reasons it had mentioned at that meeting (as recorded in paragraph 135 of document IP/C/M/50), it would be inappropriate to discuss these communications. He therefore requested that the item be removed from the Council's agenda.

162. The representative of Brazil referred to his interventions at the Council's last meeting of the TRIPS Council, and added that, according to Article 1.1 of the TRIPS Agreement, Members were free to determine the appropriate method of implementing the provisions of the Agreement within their own systems and practice. He did not support the EC proposal of searching for a coordinated response to enforcement, including the promotion of best practices and the monitoring of operational performance of national agencies in charge of combating counterfeiting and piracy. Regarding border measures, he failed to see the need to revise Article 51 of the Agreement, as implicitly suggested by the European Communities. Article 51 already contemplated the possibility of suspending the release into free circulation of counterfeit and pirated goods by customs authorities at the request of right holders.

163. The TRIPS Agreement had to be seen as an agreement in its entirety. All articles were relevant and should be addressed on a demand-driven basis for those Members seeking technical cooperation. Members who wished to raise issues relating to IPR enforcement should do so under the existing review mechanisms in the Agreement. Exchange of information on national laws and measures concerning enforcement were currently under discussion in other forums, such as the WIPO Advisory Committee on Enforcement and the WCO. The TRIPS Council already faced important challenges relating to the outstanding implementation issues under the Doha Round negotiations. His delegation was therefore not prepared to engage in an in-depth discussion on enforcement and supported China's proposal not to make this issue a permanent agenda item for the Council.

164. The representative of Australia said that it was important to take note of the EC's request that any discussion be positive and not involve finger-pointing. While he could support a discussion of border enforcement issues, he said that the outcome intended by the European Communities had to be clarified first. Given the resource and cost implications of any changes to border enforcement measures, it was important to have a more detailed analysis of the perceived problems before coming to any official view. There was also a need to consider the extent to which these issues were considered in other forums, particularly in the WCO, in order to avoid duplication of work.

165. The representative of Switzerland supported the inclusion of IPR enforcement on the Council's agenda, and the EC's proposal that the Secretariat provide a synopsis of Members' responses to the Checklist of Issues on Enforcement. The main objective should be to look at possible ways and means to assist Members in their efforts to improve enforcement mechanisms while taking into account their specific needs, in particular those expressed by developing country Members. Necessary assistance should be provided to Members that experienced difficulties in implementing

enforcement mechanisms with a view to enhancing the workability and efficiency of such mechanisms.

166. The delegation of Argentina said that issues relating to enforcement could be dealt with under the Council's agenda item on the review pursuant to Article 63.2. The proposal to make this issue a separate and permanent agenda item was not acceptable. This would be imbalanced, focusing on the interests of right holders, while not taking the objectives in Article 7 sufficiently into account, in particular the contribution of IPR protection and enforcement to social and economic welfare. She disagreed with the objectives of the EC initiative which in her view seemed to aim at amending the Agreement or establishing best practices. She also disagreed with Switzerland, which in her view seemed to consider that problems with enforcement were limited to developing countries, since counterfeiting and piracy also occurred in developed countries.

167. The representative of the United States supported the EC's proposal for a dialogue among Members on the implementation of TRIPS enforcement obligations and identifying solutions to implementation deficiencies. It agreed with the objective of examining the implementation of the TRIPS enforcement provisions in detail to understand where the main problems, difficulties and shortcomings were. Focusing on each of the individual sections in Part III of the Agreement would provide a good framework for the discussion. He agreed with the approach of examining implementation difficulties within each Section, mechanisms to address those difficulties and a coordinated response at the TRIPS level through various tools, including the promotion of best practices. He supported a discussion on border measures that would address the areas referred to in the first EC paper. Such a discussion would be beneficial in assisting countries with enforcement difficulties to gain insights into how to address those problems and to implement an effective enforcement regime under the Agreement.

168. The representative of Chinese Taipei said that an effective enforcement regime would encourage innovation and invention, and promote the development of trade and economy. He agreed with the European Communities that an effective border enforcement regime was crucial to preventing IPR infringements. It was essential that customs authorities around the world would share information and experiences. Sharing the European Communities' experiences in implementing the Council Regulations No.1383/2003 and No.1891/2004 concerning customs action against goods suspected of infringing certain IPRs would contribute to the Council's discussions on the matter.

169. Regarding the statistics contained in the latest EC communication (IP/C/W/471), he noted that the chart showing the number of articles seized, listed by origin of goods on page 8, identified Chinese Taipei as the second largest source country. However, in the other chart on the same page on the number of cases by origin of goods, Chinese Taipei did not figure among the first seven source countries. This discrepancy could be the result of a commercial dispute between an EC company and a domestic company, in which case it had nothing to do with IPR infringement and should be treated separately.

170. The efforts by Chinese Taipei to protect IPRs should not be ignored or underestimated. According to the 2005 Annual Business Infringement Report released by IFPI, its efforts to enforce IPRs had significantly reduced the number of IP infringements and it was no longer among the 31 markets with a strong presence of pirated CDs.

171. The representative of Japan said that counterfeiting and piracy was a serious problem with a global impact. The number of infringing goods suspended by the Japanese customs had grown by 47.3% from 2004 to 2005. Problems were increasing, not only in terms of volume and region, but also with regard to the scope of infringed rights that varied from conventional trademarks or copyrights to patents and designs. He hoped that the discussion in the Council would address this problem.

172. The representative of Canada reiterated its interest in addressing counterfeiting and piracy. The TRIPS Council could be an appropriate forum for a dialogue, which should not, however, duplicate discussions occurring in other international organizations. The proposed exchange of information and cooperation between customs authorities was also discussed at the WCO, which had the appropriate expertise on customs issues. She considered that a compilation of Members' responses to the Checklist of Issues on Enforcement would be useful. Her delegation had submitted its response in 1997, and would most likely have to update it.

173. The representative of India said that, while enforcement was an important issue, this was not the appropriate time to discuss it. Negotiations on some more important development issues, including those related to biopiracy, were going on and the discussion on enforcement should be deferred until those negotiations were concluded.

174. Regarding the objectives of the EC proposal, the representative of the European Communities said that paragraphs 6 and 7 of document IP/C/W/468 set out the objectives and methodology that included the identification of difficulties and the examination of appropriate mechanisms to address those difficulties. He restated that the aim of the initiative was a positive discussion, not finger-pointing.

175. He agreed with Brazil that Article 1.1 provided for the freedom of each Member to choose the appropriate method of implementing the Agreement. The initiative was not to be interpreted as an implicit attempt to revise Article 51, as suggested by Brazil. He disagreed with the Brazilian suggestion that this issue be discussed in WIPO, since TRIPS matters should be discussed in the TRIPS Council. He noted that at the latest meeting of the WIPO Advisory Committee on Enforcement, Brazil had suggested not discussing this issue in WIPO, because it was already discussed in the TRIPS Council.

176. He agreed with Argentina that Article 7 was an important provision. However, he failed to see how illegal activities, such as piracy, which were often connected to organized crime or caused public health problems, as in the case of fake medicines, could favour economic development. The assumption put forward by Argentina that the European Communities aimed at changing the Agreement was not correct.

177. He also agreed with India that biopiracy was an important issue. However, this was not the only form of piracy, and his delegation had therefore requested that the issue of enforcement be put on the agenda of the Council.

178. The representative of Brazil said that he had not said that the issue should not be discussed in the Council, since it was addressed by WIPO. Other delegations had mentioned the need to avoid duplication. His delegation had merely pointed to the fact that the WIPO Advisory Committee on Enforcement was taking care of certain issues under its competence regarding IPR enforcement in general. Many participants had sent national experts to discuss concerns regarding enforcement, including many issues regulated by the TRIPS Agreement. The allegation by the European Communities that his delegation refused to participate in that particular Committee was not correct. The Executive Secretary of the National Committee on Combating Piracy had presented national experiences at the last meeting of the WIPO Advisory Committee on Enforcement. Many different, new perspectives on measures that countries could take to combat piracy had been presented in WIPO, and it would be duplicative to repeat this in the Council.

179. He said that the Council was not empowered to enforce the TRIPS Agreement as such in Member countries. His delegation was strongly opposed to creating any diversion of functions within the WTO or fragmenting the competence of the dispute settlement mechanism, for example by tasking the TRIPS Council to examine the fulfilment of certain TRIPS provisions in an isolated manner. If

Members believed that other Members were not complying with the TRIPS Agreement, they could use the WTO dispute settlement mechanism for that purpose.

180. The TRIPS Agreement contained many provisions on public interest flexibilities and exceptions to rights that, in his view, should also be adequately enforced by Members. Moving ahead in the direction of the EC proposal would lead to an imbalance, given that these provisions were not covered by the EC proposal. This was not acceptable to his delegation.

181. The representative of the European Communities said that he failed to understand how the objective of exchanging information on best practices could imply that, as stated by Brazil, certain Members did not apply the TRIPS Agreement properly. With regard to the flexibilities referred to by Brazil, he failed to see any link between such flexibilities in the Agreement and criminal activities.

182. The Chairman noted that the views among delegations continued to differ on this issue.

183. The Council took note of the statements made.

K. INFORMATION ON RELEVANT DEVELOPMENTS.

184. The Chairman said that under this agenda item, information had usually been provided in relation to new accessions to the WTO, developments in the area of dispute settlement and, more recently, acceptances of the recent TRIPS Amendment. On this occasion, he had no new developments to report in these areas.

185. The representative of the European Communities said that he wished to raise the issue of the compliance of the United States with the DSB rulings on IP matters. In the case *US – Section 110(5) Copyright Act* (WT/DS160), a WTO panel had found, in 2000, that certain provisions of this Act were inconsistent with the United States' obligations under Section 1 of Part II of the TRIPS Agreement. The United States had been granted one year to comply with that ruling, i.e., until July 2001. However, the US Copyright Act had still not been amended. His delegation found this situation worrying, from both an individual and a systemic point of view. He posed the following three questions to the US delegation: first, were there any specific legislative initiatives in the United States to bring the Copyright Act into compliance with the TRIPS Agreement? In other words, during the past five years, had the US Congress discussed any piece of legislation aimed at amending Section 110(5) of the US Copyright Act? Secondly, what specific steps was the US administration taking to ensure that the United States would bring its Copyright Act into conformity with the TRIPS Agreement? Had there been any written communication to Congress that the United States could share with his delegation on this matter? And thirdly, when did the United States expect to finalize its work to comply with the WTO ruling, which was adopted in July 2000?

186. The representative of the United States said that, since these questions had only been raised to his delegation at the present meeting without prior notice, he was not in a position to give specific answers. He took note of the questions and, consistent with previous discussions that his delegation had had both in the TRIPS Council and in other forums on this issue, it would continue to cooperate with the European Communities. The United States intended to respond to these questions bilaterally, if that would be acceptable.

187. The representative of the European Communities said that his delegation took note of the statement of the United States and agreed with it.

188. The Council took note of the statements made.

L. OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

189. The Chairman said that the list of the 17 pending requests for observer status in the TRIPS Council by other intergovernmental organizations was contained in document IP/C/W/52/Rev.11. 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. He informed the Council that the Executive Secretary of the Secretariat of the Convention on Biological Diversity, in his letter to the Director-General dated 1 May 2006, had drawn attention to the fact that the Eighth Session of the CBD Conference of the Parties, at its meeting in Curitiba, Brazil in March 2006, had adopted decisions VII/16 and BS-III/6 to renew the application for accreditation of the CBD Secretariat as an observer at the TRIPS Council. This and other pending requests had been discussed at an informal meeting of the Council but, unfortunately, he was not in a position to report any developments in delegations' thinking concerning the pending requests. Therefore, he suggested that the Council take note of this information and agree to revert to this matter at its next meeting.

190. The Council so agreed.

M. OTHER BUSINESS

(i) Fourth annual review pursuant to paragraph 2 of the decision on the "Implementation of Article 66.2 of the TRIPS Agreement"

191. Turning to the arrangements for the Council's fourth review under the decision on the "Implementation of Article 66.2 of the TRIPS Agreement", the Chairman recalled that paragraph 1 of the Decision provided that developed country Members should submit reports annually on actions taken or planned in pursuance of their commitments under Article 66.2. To this end, they had to provide new detailed reports every third year and, in the intervening years, provide updates to their most recent reports. These reports had to be submitted prior to the last Council meeting scheduled for the year in question. Paragraph 3 of the Decision determined the information that had to be provided in these reports. He recalled that the first set of detailed annual reports under the Decision had been presented to the Council's meeting in November 2003, and two sets of updates to the Council's meetings in December 2004 and October 2005. Therefore, this year, developed country Members should submit new detailed reports on actions taken or planned in pursuance of their commitments under Article 66.2 prior to the Council's end of year meeting that had been scheduled for 25-26 October. As provided in paragraph 2 of the Decision, the Council should review these updates at that meeting. He therefore suggested that developed country Members be requested to submit new detailed reports on actions they had taken or planned in pursuance of their commitments under Article 66.2 by 29 September 2006, i.e. approximately three weeks before the meeting, in order to allow their timely circulation and review at the Council's meeting in October.

192. The Council so agreed.

(ii) Other Reviews

193. The Chairman reminded Members of certain other reviews that would be on the Council's agenda at its next meeting in October. As he had already indicated under an earlier agenda item, the Council would take up its annual review of technical cooperation. Furthermore, the Council would need to hold its third annual review under paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health, and report on its operation to the General Council. Finally, the Council would have on its agenda the fifth transitional review under Section 18 of the Protocol on the Accession of the People's Republic of China.

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