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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

Held in the Centre William Rappard on 1 March 2011

Chairperson: Mr. Martin Glass (Hong Kong, China)

The present document contains the record of the discussion which took place during the Council for TRIPS meeting held on 1 March 2011.

Subjects discussed — Page nos.

A. NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

1. The Chairman said that, since its meeting in October 2010, 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:

- China had notified its revised Patent Law, which *inter alia* implemented the WTO Decision on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", providing the legal basis for China to act as an exporting Member, as well as an importing Member, where a national emergency or any extraordinary state of affairs occurred, or public interests so required. This notification had been received just after the Council's previous meeting and, as had been agreed by the Council at that meeting, reference to it had been added to the Council's report to the General Council on its review of Paragraph 6 System;[1]

- Chinese Taipei had supplemented its list of "other laws and regulations" with information concerning its Patent Attorney Act;

- Israel had notified laws on appellations of origin and geographical indications, on copyright and on patents, as well as ordinances on designs and trademarks;

- Barbados haw notified amendments to its copyright act and related regulations, an Intellectual Property (Miscellaneous Provisions) Act, and a Patents (Priority Protection) Order Act; and

- Finland had notified amendments to its laws and regulations on copyright, trademarks, collective marks, geographical indications, designs, patents, plant variety rights, utility models, layout-designs of integrated circuits, protection of undisclosed information, and on the openness of government activities. In addition, it had notified legislation relating to the prevention of the abuse of intellectual property rights, civil judicial procedures and remedies, provisional judicial measures, special requirements related to border measures, criminal procedures and penalties, administrative procedures and remedies, and other laws.

These notifications were being circulated in the IP/N/1- series of documents.

2. The Chairman urged those Members whose initial notifications remained incomplete to submit the outstanding material without delay. He also reminded other Members of their obligation to notify any subsequent amendments of their laws and regulations without delay after their entry into force. He in particular reminded those Members who had made any changes to their laws and/or regulations to implement the Decision on TRIPS and public health and who had not yet notified such changes to the Council to do so.

3. As regards notifications of contact points under Article 69 for the exchange of information and cooperation on trade in infringing goods, he said that, since the Council's meeting in October, Lesotho had notified its contact point. In addition, updates to contact points notified earlier had been received from the European Union and Latvia.

4. The Council took note of the information provided.

[1] Document IP/C/57 and Corr.1.

B. REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

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

6. Turning to the arrangements for the review of Maldives' implementing legislation, he said that, at the meeting of the General Council on 14 December 2010, Maldives had informed Members that it would graduate from the United Nation's list of least developed countries as from 1 January 2011, as decided by the United Nations General Assembly in 2005.

7. The representative of Maldives said that Maldives was no longer an LDC as of 1 January 2011 and a beneficiary of special and differential treatment accorded to the LDCs. Therefore, she wished to inform the Council of the status of its on-going work towards compliance with TRIPS obligations as a non-LDC.

8. The IP regime of Maldives was still in the process of development, although IP protection had been an explicit policy goal of the Government in the past few years. Maldives had joined WIPO in 2004 for the purpose of developing an effective IP regime. Since then, various technical assistance programmes had been sought from WIPO, including technical advice on the establishment of a modern Intellectual Property Office in January 2004. In advising the Government, WIPO had recommended to formulate a national IP strategy based on a careful identification and selection of intellectual property policy options that would best serve the social and economic development needs of Maldives. However, like in many other developing countries, IP remained a novel field for policy makers, the business community and for the general public. Maldives needed sufficient analytical capacity and perhaps examples of best practices to help its policy makers to discuss IP issues and link related opportunities to developmental policies.

9. Notwithstanding these capacity constraints, Maldives had passed a law governing copyright and related rights in October 2010. The Law No 23/2010 had been enacted to establish the standards for copyright and related rights required by the TRIPS Agreement. Furthermore, an Industrial Property Act had been drafted in English. The Industrial Property Act was being translated into Maldives' official language Dhivehi for debate in Parliament. The Copyright Law (Law 23/2010) was presently only available in Dhivehi and was being translated back to English, primarily for the purpose of notification to the WTO. The law was available at http://trade.gov.mv.

10. WIPO's technical assistance, especially in drafting the laws, was of immense value. Maldives and WIPO had agreed on a work programme, the specific aim of which was to fully comply with TRIPS obligations. She expressed her delegation's gratitude for WIPO's support.

11. As she had also mentioned at the General Council's meeting in December 2010, the graduation from LDC status had brought new challenges, which Maldives was dealing with in spite of its vulnerability and lack of capacity. Moreover, Maldives had been undergoing a democratic transition for the past few years that had included the formulation of a new Constitution in 2008 and relevant laws. The on-going work on the legislative agenda had put a heavy burden on Parliament to expedite the laws necessary for the compliance with Maldives' international legal obligations. Nonetheless, Maldives remained committed to its TRIPS obligations and willing to work with relevant organizations and its development partners, including with WIPO, to fulfil the notification and review requirements. She appealed to the understanding of the membership in relation to Maldives' initial notification.

12. The Chairman suggested that the Council request the Secretariat to remain in contact with the delegation of Maldives concerning TRIPS notification and review procedures, and that the Council come back to the arrangements for the review of Maldives' implementing legislation later this year, once the Council had received the necessary notifications of laws and regulations.

13. The Council took note of the statements made and 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

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

15. He recalled that, at the Council's meeting in October 2010, India had suggested that the Council invite the CBD Secretariat to brief the Council on the outcome of the tenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP10) held in Nagoya, Japan in October 2010. In the context of his consultations with a number of delegations on the pending requests for observer status by intergovernmental organizations, Members had not reached agreement on that suggestion. However, in the course of those discussions, Japan had expressed its willingness to make a presentation, in its capacity as the host country of COP10, on the outcome of the meeting. He suggested that the Council offer the floor to Japan to make the presentation before opening the floor for discussion. He also informed the Council that Bolivia wished to introduce a room document on the review of Article 27.3(b) of the TRIPS Agreement.[2]

16. The representative of Japan said that COP10 had been held from 18 to 29 October 2010 at the Nagoya Conference Centre and that more than 13,000 participants had attended, including delegates from member countries, representatives of indigenous peoples and civil societies. The conference had been accompanied by about 350 side-events, among which the Interactive Fair for Biodiversity had attracted more 11,800 participants. One of the major outcomes of COP10 was the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol) and the Strategic Plan for Biodiversity 2011-2020.

17. He said that the CBD had started its work on access and benefit sharing in 2000 by establishing an Ad-Hoc Open-Ended Working Group on Access and Benefit Sharing. The Eighth Meeting of the Conference of the Parties to the Convention on Biological Diversity had instructed the Working Group to complete its work with regard to the international access and benefit-sharing regime at the ear1iest possible time before COP10. That target had successfully been achieved by the adoption of the Nagoya Protocol at COP10 after nine meetings of the Working Group.

18. Under the Nagoya Protocol, each Party should take concrete measures to implement effectively the third objective of the CBD, i.e. the fair and equitable sharing of the benefits arising from the utilization of genetic resources, and other relevant provisions. The Nagoya Protocol had been open for signature by Parties since February 2011 and would enter into force on the 90th day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession by Parties.

[2] Subsequently circulated as document IP/C/W/554.

19. He said that the Nagoya Protocol would facilitate access to genetic resources and promote their utilization because of transparency, clarity and legal certainty of access and benefit-sharing legislation in providing countries. The Protocol would contribute to the conservation and sustainable use of biological diversity through facilitating fair and equitable benefit sharing. The Protocol would enable and strengthen the compliance with domestic access and benefit-sharing legislation or regulatory requirements through the collection of information related to prior informed consent and mutually agreed terms at designated checkpoints. The Protocol would enable fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources according to mutually agreed terms with indigenous and local communities holding such knowledge, thereby contributing to respect, preservation and maintenance of their knowledge.

20. Article 6 of the Nagoya Protocol obliged each Party to take measures to improve access to genetic resources, including to provide for transparency and clarity of domestic access and benefit-sharing legislation or regulatory requirements, information on how to apply for prior informed consent, a written prior informed consent decision, for the issuance of a permit or its equivalent as evidence of a decision to grant prior informed consent. Article 5 confirmed the principle of Article 15 of the CBD that the monetary and non-monetary benefits arising from the utilization of genetic resources shall be shared in a fair and equitable manner and that such sharing shall be upon mutually agreed terms.

21. Article 15 of the Protocol provided that each Party shall take appropriate, effective and proportionate measures to provide that genetic resources utilized within its jurisdiction had been accessed in accordance with prior informed consent and that mutually agreed terms had been established. Article 17 stipulated the designation of one or more checkpoints to collect information related to prior informed consent and mutually agreed terms as one of the measures to be taken by parties to support compliance. Article 17 also provided that the information related to prior informed consent, the source of genetic resources, the establishment of mutually agreed terms, and the utilization of genetic resources would be provided to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate, and that checkpoints should be relevant to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization. Those provisions provided effective and flexible measures to ensure each party's compliance with the CBD while taking into account their own national policies and other situations.

22. He said that the Nagoya Protocol had several provisions related to traditional knowledge associated with genetic resources. For example, Articles 5, 7 and 12 provided that each Party shall take measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources were shared in a fair and equitable manner upon mutually agreed terms. There were provisions related to access for non-commercial research purposes, cases of emergencies and the relationship with international agreements and instruments. Article 10 provided for global multilateral benefit-sharing mechanism to address the sharing of benefits derived from the utilization of genetic resources that occurred in transboundary situations or for which it was not possible to obtain prior informed consent. There were also provisions related to the evaluation of its effectiveness.

23. In conclusion, he said that constructive solutions had been reached on three contentious issues, i.e. derivatives, compliance and retroactive application due to efforts made by the participants. It was the responsibility of each Party to cooperate with each other for the successful implementation of the Nagoya Protocol.

24. The representative of the Plurinational State of Bolivia said that, as stated in document IP/C/W/545, the review of Article 27.3(b) was part of the mandate of the Doha Work Programme under paragraph 19 of the Ministerial Declaration. It was an implementation-related issue

under paragraph 12 of the Ministerial Declaration, which mentioned the adoption of a Decision to address implementation problems (WT/MIN(01)/17) and stated that "negotiations on outstanding implementation issues shall be an integral part of the Work Programme".

25. In the 15 years since the adoption of Article 27.3(b), WTO Members had witnessed a race to patent life forms and parts thereof, a trend that was extremely worrying given its ethical and moral implications and its adverse effects in areas of major importance to developing countries, such as agriculture, food, climate change and health.

26. Article 27.3(b) established Members' obligation to grant patents for micro-organisms and microbiological and non-biological processes. That provision also allowed Members to award patents for plants, animals and biological processes, thus promoting a new phase in which capitalism expanded into nature in a way that had never been seen before, and which amounted to the privatization of life itself. Consequently, the last 15 years had seen a proliferation of patents and patent applications concerning a wide range of life forms, including human life itself or parts thereof, such as proteins, genes, gene sequences, cells, cell lines and tissue.

27. Many reports had documented that phenomenon. In 1999, 918 patents had been awarded for rice, maize, soya and sorghum seed; most of those had gone to just six multinational corporations. In 2000, an investigation had revealed that patents had been pending or had been granted on more than 500,000 genes or partial gene sequences of living organisms. Of those, over 9,000 patents involved 161,195 whole or partial human genes. In 2005, a study had shown that nearly 20 per cent of all human genes had been patented in the United States, in other words 4,000 of almost 24,000 human genes.

28. The patentability of life forms promoted by Article 27.3(b) raised serious ethical and moral concerns for many cultures and populations around the world. Those concerns had been raised on a number of occasions by groups of developing countries and international bodies. For example, according to the 1999 United Nations Human Development Report, the current patent system was leading to "a silent theft of centuries of knowledge from developing to developed countries".

29. The extension of patents to life forms was based on the idea that life forms and parts thereof were human inventions and, as such, patentable. That concept promoted the commercialization of life and nature, reducing their value to nothing more than a mercantile and commercial vision. Such a vision was far removed from the culture, values and beliefs of many peoples and societies, for whom life was something sacred and special that could not be considered a human invention or treated as just another commodity. Above all, its use should not be monopolized by a select few.

30. A system that treated human beings and their vital characteristics as merchandise reduced the value of life to an economic value and consigned humanity to a lower level of moral development. Humanity and human progress should not be measured only in economic and commercial terms, but rather in terms of human values and dignity.

31. A serious consequence of Article 27.3(b) had been the concentration of patents on life forms in the private sector, most notably in the hands of a few multinational corporations based in developed countries. The situation was especially worrying in the seed sector, where 67 per cent of the market was controlled by the ten largest corporations, and around 40 per cent by only two of them. That situation could also be seen in other areas of biotechnology and should be taken very seriously indeed.

32. Patents on life forms also had a negative impact in terms of access. Some developing countries were concerned that the rights afforded to patent holders could restrict the use of their genetic resources, as well as the use of those resources by indigenous peoples. Patents on life forms

and parts thereof could also adversely affect the exports and commercial activities of developing countries.

33. The granting of patents on life forms and parts thereof was often justified on the basis that it encouraged innovation and promoted research. However, there was increasing evidence that that premise was not entirely true, and that dominant and concentrative model also frustrated innovation, stifled research and had a negative impact on scientific progress, something already highlighted by numerous academics, experts and even Nobel Prize winners in a broad range of scientific fields.

34. The effects of allowing the patenting of life forms and parts thereof were particularly felt in the area of agriculture and food due to the unprecedented control of the food chain by a small number of corporations. The combination of the concentration of market control with the ability to patent had paved the way for a comprehensive takeover of genetic resources, seeds and by-products by certain corporations, which had led to a greater concentration of power and, in turn, ever increasing food prices, the inhibition of agricultural innovation and the undermining of farmers' rights. That constituted an assault on the foundations of age-old traditional farming practices and undermined one of the farmers' oldest rights, which was to save, harvest and replant seeds.

35. The negative impact of biological material patents in the area of food had been condemned on a number of occasions. For instance, the UN Special Rapporteur on the right to food had informed the General Assembly that "the expansion of intellectual property rights can constitute an obstacle to the adoption of policies that encourage the maintenance of agrobiodiversity and reliance on farmers' varieties. Intellectual property rights reward and encourage standardization and homogeneity, when what should be rewarded is agrobiodiversity, particularly in the face of the emerging threat of climate change […]. In addition, intellectual property rights […] can constitute a direct impediment to innovation by farmers". Another noteworthy factor was that the companies concerned were starting to profit from one of the most dangerous threats to humanity, climate change. Several corporations had joined the race to patent plants and parts thereof that could represent strategic resources for mankind in the future.

36. In 2008, a report by the ETC Group had revealed that some 532 patents had been requested by or granted to corporations for plants and genes that were resistant to climate change (otherwise known as "climate ready" due to their resistance to drought, floods and frost). Although the historical responsibility for climate change lay with developed countries, it could be anticipated that such action might lead to developing countries being asked to pay for access to resources that, in many cases, they themselves had developed and that were critical for combating climate change.

37. The public health consequences of allowing the patenting of life forms and parts thereof could also be very severe. Such patents could have a negative effect on innovation in the sector, impede access to relevant technologies and hamper access to medicines, vaccines and essential treatment for those unable to pay for them.

38. That new phase of capitalism focused on patenting and privatizing life. There was economic greed to patent life. And yet the patenting of biodiversity, seeds and related medicines posed a significant threat. The process led to a proliferation of laws and policies under which life was considered a patentable material, whereas in the past it had been unthinkable to treat life and any part of it as an object or something that could be patented.

39. In conclusion, he emphasized that the patenting of life forms was simply unacceptable. The patenting of life forms posed a serious danger to all mankind, but in particular to developing countries. The control of life forms and parts thereof lay in the hands of a few multinationals based in developed countries. Such corporations might eventually be allowed to exercise a monopoly over the use of those life forms and parts thereof. That situation was critical for developing countries, for

which important decisions relating to food, health and climate change would be resolved in the interests of maximizing profits rather than the well-being of mankind. Patents on life forms and parts thereof threatened the traditional practices of indigenous farmers and peoples, as well as the exports of developing countries. The costs of such a system exceeded the benefits. That problem affected all of mankind and required an international solution. Bolivia therefore proposed that Article 27.3(b) be amended to prohibit the patenting of all life forms and parts thereof. In the view of his delegation, that was an essential part of the Doha Development Round mandate and the best contribution that the WTO could make to achieve the development objectives.

40. The representative of Ecuador said that the Bolivian room document reaffirmed the need for in-depth discussions on the prevention of biopiracy and misappropriation and that the Council should consider and debate that document.

41. The representative of China said that, given the complexity of the issue of the patenting of life forms, the Council should further study its impact and come up with tangible solutions in the future.

42. She thanked the delegation of Japan for its presentation on the Nagoya Protocol, but expressed her disappointment that the CBD Secretariat was not able to make such a presentation as they had done at WIPO and the WHO.

43. She said that Articles 15 and 16 of the Nagoya Protocol provided that each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources and associated traditional knowledge utilized within its jurisdiction had been accessed in accordance with prior informed consent and that mutually agreed terms had been established as required by domestic access and benefit-sharing legislation or regulatory requirements of the other party. Parties shall, as far as possible, and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements.

44. Given that patents were important in the utilization of genetic resources and associated traditional knowledge, WTO Members should take appropriate and effective measures in patent applications to avoid misappropriation. According to the Doha Declaration, the review of Article 27.3(b) should include the examination of relationship between the TRIPS Agreement and the CBD. The TRIPS Agreement, the CBD and the Nagoya Protocol should operate in a mutually supportive manner. Mandatory disclosure requirements would improve the transparency of the utilization of genetic resources and associated traditional knowledge, help to prevent misappropriation and avoid erroneous patents, and bring little burden to patent applicants and patent authorities.

45. The Director-General's consultations on the issues of TRIPS/CBD and GI extension had provided opportunities for detailed technical discussions without getting trapped in theological issues. She said that the issues of TRIPS/CBD and GI extension were both implementation-related issues in the Doha Round, negotiations on those issues must be an integral part of the work programme and the outcome of those two issues must be part of the Single Undertaking. Noting that the negotiations on the issue of GI register had developed a draft legal text, she called upon the Director-General to continue his consultations and move to text-based consultations as early as possible.

46. The representative of Canada requested that a two-page submission her delegation had provided in the context of the Director-General's recent informal consultations on the relationship between the TRIPS Agreement and the CBD be taken on record.[3] On 17 February 2011, Canada and 16 other Members had discussed how misappropriation of genetic materials and associated traditional knowledge were addressed in various national systems. That two-page submission, along with the subsequent discussions, served to reinforce Canada's understanding that there were already a

[3] Canada's submission is included in an Annex to the present record.

multitude of different approaches in use to address the issue of misappropriation. Those differences were particularly apparent amongst those calling for a TRIPS amendment that would provide for mandatory disclosure requirements, prior informed consent and access and benefit sharing.

47. In the view of her delegation, the TRIPS Agreement and the CBD co-existed in a mutually supportive manner, and that view had only been reinforced in the Nagoya Protocol. To that end, she was disappointed that some Members suggested, in the post-Nagoya context, that the revised overarching priority should be for the TRIPS Agreement to become an enforcement mechanism for the CBD. Nevertheless, her delegation was encouraged by a positive development emanating from the Director-General's informal consultations. Specifically, the two-page submissions submitted by Canada and 16 other Members could serve as a useful stepping stone for more productive discussions in the TRIPS Council, where the discussion had become rather stale over the past number of years, and Members had been polarized and seemingly paralyzed as to what to do next.

48. She said that tested and concrete solutions were available to address the issue, including third party prior art submissions, databases, contracts and codes of conduct, which had a positive and effective track record. Intellectual property systems provided for a number of useful tools to help prevent the misappropriation of genetic materials and associated traditional knowledge. One tool was the possibility of an unsolicited filing of prior art by a third party. In addition, databases could play an important role in helping patent examiners establish the novelty of an invention, and could, in turn, protect holders by helping to prevent erroneously granted patents.

49. While some Members had made worthwhile proposals to that effect in the TRIPS Council, including Japan's proposed one-click database systems, prior art databases merited consideration as a means to help ensure the harmonious co-existence of the TRIPS Agreement and the CBD because they were already being used by patent offices worldwide. India's Traditional Knowledge Digital Library was one concrete example, and the Canadian Intellectual Property Office was pleased to have it in its toolbox. Other examples included the Korean Traditional Knowledge Portal, the Chinese Traditional Chinese Medicine Patents Database, the System-Wide Genetic Resources Programme of the Consultative Group on International Agricultural Research, and the World Bank's Indigenous Knowledge Databases. Much could be achieved by better connecting existing databases to patent systems, encouraging the creation of new databases, and ensuring easy and one-step access by patent examiners to those important resources.

50. The multitude of genetic resources, users and holders made every case of access unique and largely a matter of private law between holders and users. As such, contracts were worthwhile in that they recognized that uniqueness and provided a solution tailored to a specific user and holder of that genetic resource, directly linking all without intermediaries. In addition to being a means to help prevent the misappropriation of genetic resources and associated traditional knowledge, contracts could directly lead to both upfront and on-going financial benefits to the holder - unlike any mandatory disclosure requirement.

51. All the Members should acknowledge that access to genetic resources and associated traditional knowledge was, at least partly, a matter of corporate social responsibility and awareness. Indeed, in some cases, awareness by a potential user of an indigenous or local community's strong bond with genetic resources or associated traditional knowledge might simply be lacking. Members, individually and collectively, could be instrumental in raising that awareness and in promoting the adoption by companies of codes of conduct or guidelines on access to genetic resources and associated traditional knowledge, including as new elements of existing corporate social responsibility strategies. That could also be expanded to a multi-stakeholder approach, with industry-wide standard-setting, independent certification and associated labelling. Such approaches had been successfully implemented in the areas of sustainable forestry, humane animal treatment, and fair trade. Companies had become more responsible, communities had been empowered, and consumers were better

informed. A similar approach for the access to genetic resources and associated traditional knowledge was certainly not out of reach.

52. In closing, she invited other Members to reflect on and discuss the above-mentioned alternative mechanisms, which provided concrete and realistic ways ahead. The more widespread adoption of measures and instruments such as databases, contracts and codes of conduct would reinforce well-equipped patent systems. The broad patent system based on the fundamental principles of novelty and inventiveness would not only prevent the erroneous granting of patents but also prevent the misappropriation of genetic resources and traditional knowledge.

53. The representative of Korea said that Article 27 of the TRIPS Agreement allowed Members to decide the patentability of life forms and provided permissible exclusions from patentable subject matter based on public order and morality. Bolivia's proposal to prohibit the patenting of life forms might hamper the development of new technology, especially biotechnology. Innovation in the pharmaceutical and biotechnology industries enhanced the quality of life and living standards, and deserved adequate patent protection.

54. He shared some Members' concern over biopiracy and misappropriation of genetic resources, but believed that the TRIPS Agreement was not a proper tool to address the objectives of the CBD. He doubted whether the disclosure requirement was an effective solution to prevent erroneously granted patents. In his view, the disclosure requirement could be burdensome for patent applicants and inevitably cause instability in patent systems. He sought clarification as to whether and how the disclosure requirement could effectively help to address erroneous patents.

55. He said that since the objectives of the TRIPS Agreement and the CBD were entirely different, his delegation could not agree to amend the TRIPS Agreement. Nevertheless, his delegation was willing to engage constructively in finding solutions to protect biodiversity and prevent biopiracy and misappropriation of genetic resources.

56. The representative of Bolivarian Republic of Venezuela thanked the delegation of Japan for its presentation on the Nagoya Protocol, while regretting that the presentation had not been made by the CBD Secretariat. He supported Bolivia's submission, and said that the review of Article 27.3(b) was an outstanding issue of the Doha Agenda. Article 27.3(b) provided for the possibility of patenting micro-organisms or microbiological processes. The Constitution of the Bolivarian Republic of Venezuela expressly prohibited the patenting of life forms. In Nagoya, his delegation disagreed to the text of the Nagoya Protocol on the ground that it had diverted from its original objectives and had not covered the fundamental principles that had guided its drafting and the spirit in which it had been conceived. On the question of access to genetic resources, the sovereignty of States and their indigenous peoples over their biological resources was reaffirmed, and the authority to permit access to genetic resources therefore lay with national governments and was subject to national legislation.

57. Article 1 of the Nagoya Protocol provided for the fair sharing of benefits in order to guarantee biodiversity. Accepting this principle would be as repugnant as to declare that the distribution of benefits in the field of arms production, between producers and buyers, would ensure peace. Nothing was further from the truth: all production of weapons was a path leading inevitably to aggression and any possibility of patenting biodiversity could be the path leading to the end of the historical tradition of collective ownership of resources that stood in contradiction to the law of patents. Patents involved individual monopolies and the possibility of appropriating and eliminating resources that had been preserved virtually intact for thousands of years, passing from generation to generation and were, in many cases, considered by indigenous peoples as sacred. That ethical and moral principle would be impaired if patenting of life was to be authorized.

58. Article 4 of the United Nations Declaration on the Rights of Indigenous Peoples established the right of indigenous peoples to self-determination, given that it was precisely States in which those communities were present that had systematically violated their rights. Article 5 established the right of such peoples to maintain their distinct economic, legal, political and social rights, which would undoubtedly be violated by the patenting of life forms. Traditional resources should not come within the purview of intellectual property rights, and in the case of Venezuela, its sovereignty would be violated.

59. The representative of Brazil thanked the delegation of Japan for its presentation of the Nagoya Protocol, although she wished that the CBD Secretariat had made such a presentation. She said that the approval of the Nagoya Protocol had increased the importance of the discussion in the TRIPS Council on how Members could establish a mutually supportive relationship between the TRIPS Agreement and the CBD. There were clear international parameters on prior informed consent and access and benefit sharing that would guide countries in designing their national legislation. The TRIPS Agreement had an essential role to play in ensuring prior informed access to genetic resources, achieving equitable sharing of benefits arising from the use of traditional knowledge and genetic resources, and preventing erroneous patents.

60. By linking patent processing with the observance of national laws on prior informed consent and access and benefit sharing, the patent system could be an important tool in helping compliance with such laws. If patent applicants knew that they would be asked to disclose the source or origin of genetic resources or associated traditional knowledge anywhere in the world and the processing and validity of patents depended on the veracity of that information, they would have a strong incentive to comply with national laws. Such objectives could not be achieved either by contractual arrangements or prior art procedures. Contractual arrangements on access to genetic resources and fair and equitable sharing of benefits were already in place in many national laws including in Brazil. Contracts might work well if they were respected. The problem would arise when there was a need to verify and ensure compliance, especially when genetic resources or associated traditional knowledge in question were taken out of the country. Another open question was how to prevent those who had not complied with prior informed consent and access and benefit sharing requirements from profiting from their illegal acts. Without a disclosure requirement in patent applications, there was no way to know that genetic resources were utilized in the patented invention and compliance would depend entirely on the good faith of collectors.

61. Turning to prior art requirements, she said that it was more a way of avoiding the grant of erroneous patents than of preventing misappropriation. Even as a means of preventing erroneous patents it was unrealistic for patent offices to have information on all genetic resources and associated traditional knowledge. Even if database systems were established, they could never account for the entire universe of genetic resources and associated traditional knowledge in all possible forms, especially because a great part of such resources were still unknown. It would also be difficult to justify the high cost involved in that endeavour, especially in comparison with the cost of a simple checkbox under the disclosure requirement. In conclusion, her delegation was in favour of amending the TRIPS Agreement to include a mandatory requirement. Patent applicants should inform the providing country and the country of origin of genetic resources and associated traditional knowledge utilized in inventions, and comply with prior informed consent and access and benefit-sharing legislation. The disclosure requirement was the most effective and least burdensome way for the TRIPS Agreement to support the compliance with the CBD and the Nagoya Protocol.

62. The representative of Australia said that his delegation had actively participated in the negotiation of the Nagoya Protocol and welcomed the outcome. Referring to Bolivia's proposal of the patenting of life forms, he said that the current flexibilities under Article 27.3(b) of the TRIPS Agreement were sufficient to allow Members to take the decision on the patentability of life forms in accordance with their national policies. He supported the intervention by Canada. As a mega-diverse

country with a unique indigenous culture, Australia had a strong interest in equitable access to genetic resources and associated traditional knowledge. As a Party to the CBD, Australia shared the relevant CBD objectives. Australia's national experience indicated that effective benefit-sharing regimes could be implemented without making changes to patent systems. Australia's access and benefit-sharing systems was consistent with its obligations under the CBD. Under Australia's access and benefit-sharing systems, a permit was required to obtain access to biological resources for research into their genetic and bio-chemical properties. Streamlined permanent arrangements applied for non-commercial research. A benefit-sharing agreement was required before a permit for commercial research could be issued, and prior informed consent of indigenous owners was required when the genetic resources were on indigenous peoples' land. The benefit-sharing arrangement must include protection for and valuing of indigenous peoples' knowledge to be used. The Australian Government had developed a model benefit-sharing agreement, including suggested monetary and non-monetary benefits and addressing intellectual property ownership. All agreements to date had followed the model closely.

63. Finally, he said that his delegation was prepared to engage constructively in discussions in international forums. Nevertheless, it considered that the disclosure requirement merited further consideration in conjunction with other options. The Director-General's consultations on the TRIPS/CBD issue had been productive, but there were a range of central policy issues yet to be resolved. Many of those depended on the details lacking in the proposal contained in document TN/C/W52, including the nature and scope of the proposed disclosure requirement, which underlined the need for detailed technical consideration of all options taking into account the work in other forums.

64. The representative of Angola, speaking on behalf of the LDC Group said that the Group was particularly interested in ensuring that the outcome of the review of Article 27.3(b) did not constrain LDCs from using the TRIPS Agreement to advance national development interests nor result in situations that would run counter to morality. As indicated in paragraph 19 of the Doha Ministerial Declaration, the discussions on the review of Article 27.3(b) were closely linked to the discussions on the relationship between the TRIPS Agreement and the CBD as well as the protection of traditional knowledge and folklore.

65. He reiterated that the LDC Group's position was that life forms should not be patented and that the review of Article 27.3(b) should clarify the patentability of plants and animals as well as microorganisms and all other living organisms and their parts. Further, natural processes for the production of plants, animals and other living organisms should not be subject to patent protection. Meanwhile, it was important to maintain the flexibility of the *sui generis* system for the protection of plant varieties. The *sui generis* system could be developed and implemented by the individual country based on its own needs, which would contribute to improving food security by ensuring that indigenous peoples' inventions were protected and access to seed guaranteed.

66. He thanked the delegation of Japan for its exhaustive presentation on the Nagoya Protocol, which paved the way for negotiations on the TRIPS/CBD issue in the WTO. He appreciated the efforts undertaken by the Director-General Pascal Lamy to conduct parallel informal consultations on the issues of TRIPS/CBD and GI extension. Those consultations were useful in allowing Members to acknowledge existing legal regimes to prevent misappropriation and protect geographical indications. He said that biodiversity was an important resource of the livelihood of populations living in rural areas in most LDCs, yet benefits arising from the appropriation of such resources and the use of traditional knowledge by multinational corporations had barely been shared with the communities concerned. That issue should be addressed through introducing a mandatory disclosure requirement into the TRIPS Agreement. Meanwhile, it was equally important to ensure that patent applicants demonstrated that they had obtained prior informed consent from competent authorities in the country

of origin of genetic resources and that arrangements to facilitate the sharing of the benefits arising from the appropriation of such resources and/or traditional knowledge were in place.

67. The representative of Nigeria thanked the delegation of Japan for its presentation, and said that he preferred that the CBD Secretariat make such a presentation. He said that the African Group and other Members were demanding the protection of genetic resources and associated traditional knowledge through a mandatory disclosure requirement as proposed in document TN/C/W/52. The disclosure requirement would, in addition to combatting biopiracy, strengthen the credibility of patent systems through the facilitation and assessment of novelty and inventiveness criteria, thereby assuring that the patent system did not issue bad patents.

68. He appreciated the consultations being held by the Director-General in accordance with paragraph 39 of Hong Kong Declaration and said that those consultations had provided opportunities for detailed technical discussions without getting into the issue of mandate. He hoped that those consultations would lead to the amendment of the TRIPS Agreement.

69. The representative of India said that the presentation made by the delegation of Japan provided an overview of the Nagoya Protocol, but did not always give the needed details of substantive provisions. Many developing countries believed that there were limitations in the Nagoya Protocol to tackle the misappropriation of genetic resources and traditional knowledge in patent applications and that the solution lay in the amendment of the TRIPS Agreement to include mandatory disclosure requirements. He reiterated his delegation's request for the CBD Secretariat to make a presentation in the WTO, as the CBD Secretariat had already done so in WIPO. He supported the statements made by the delegations of Brazil and China.

70. He conveyed his sense of disappointment at the lack of progress on the TRIPS/CBD issue despite a clear mandate, nine years' extensive technical work, and the overwhelming support of the majority of the WTO Membership. He said that it was time to start text-based negotiations as an integral part of the Single Undertaking and that an outcome on the TRIPS/CBD issue was essential for India as a development tool deliverable in the Doha Round.

71. The representative of Peru shared the concerns raised by the delegations of China, Brazil, India and others. He regretted that the CBD Secretariat was unable to make a presentation in the TRIPS Council. Referring to the linkage between the TRIPS Agreement and the CBD, he said that the CBD recognized States' sovereign right over their genetic resources, while the TRIPS Agreement allowed the patenting of genetic resources, which was not equivalent to biopiracy, but did not guarantee the compliance with prior informed consent and fair and equitable benefit sharing as provided in the CBD and the Nagoya Protocol. Therefore, his delegation advocated an amendment to the TRIPS Agreement, which would bring the TRIPS Agreement in line with the CBD. Since 2003, his delegation had tabled several working documents on the amendment to the TRIPS Agreement in the WTO and other forums. To introduce the disclosure requirement into international systems would be an effective way to deal with the misappropriation of genetic resources and traditional knowledge, as it would request patent applicants to identify the country of origin of genetic resources as well as provide the evidence of prior informed consent and fair and equitable benefit sharing. The amendment proposal would ensure the compatibility between the TRIPS Agreement and the CBD.

72. He acknowledged the importance of the intellectual property system as a tool to promote economic, social and cultural development, while indicating the need to improve the system by preventing the misappropriation of genetic resources. As one of the co-sponsors of document TN/C/W/52, he said that Peru was not trying to impede the use of genetic resources, but wanted to protect genetic resources against biopiracy. The disclosure requirement would help to recognise the States' right over their genetic resources and therefore provide countries with development opportunities. The disclosure requirement would also help to make an appropriate balance between

intellectual property system, especially the patent system, and the needs of indigenous communities in developing countries.

73. The representative of South Africa said that the relevance of the Nagoya Protocol to the work of the TRIPS Council was obvious. A large group of developing countries had proposed an amendment to the TRIPS Agreement in order to introduce a mandatory disclosure requirement in patent applications in accordance with document WT/GC/W/590. In that document, patent applications were required to include the origin of biological resources and/or associated traditional knowledge, prior informed consent and access and benefit sharing. In that context, he welcomed Article 6 of the Nagoya Protocol that required Members to take steps to ensure prior informed consent to be obtained, and Article 5 that recognised that the benefits arising from the utilization of genetic resources be shared in a fair and equitable manner.

74. He said that, while national approaches were a step in the right direction, such diverse approaches might fall short of ensuring the universal accrual of benefits from the use of genetic resources. The best guarantee for achieving such benefits lay in the amendment of the TRIPS Agreement by requiring mandatory disclosure. He reiterated his delegation's call for inclusion of the CBD Secretariat in the work of the TRIPS Council and said that the relationship between the CBD and the TRIPS Agreement should be further articulated in light of developments and guidelines provided by the Nagoya Protocol.

75. The representative of Indonesia supported the discussion on the patentability of life forms with a view to having a clear perspective. He urged all Members to engage in constructive discussions, and make substantive progress on the issues of TRIPS/CBD and the protection of traditional knowledge and folklore. Given the importance of those issues to developing countries, he reiterated the urgency of amending the TRIPS Agreement to include a disclosure requirement. As an organization that valued development, the WTO must come up with rules and parameters that would enhance and benefit development. The potential of genetic resources and traditional knowledge could become one of key elements for economic welfare for people in developing countries. Given the adoption of the Nagoya Protocol, he also urged all Members to take necessary steps to incorporate the principles of the CBD and the Nagoya Protocol into the TRIPS Agreement. It would be in the best interest of all Members to articulate how to afford sufficient protection of genetic resources and how to establish fair practices of the use of genetic resources.

76. The representative of the European Union reaffirmed his delegation's commitment to the Nagoya Protocol, and said that the European Union would ratify and implement it as soon as possible.

77. He said that Bolivia's document addressed the important issue of patenting of life forms and expressed ethical and moral concerns. However, his delegation was not in favour of amending Article 27.3(b), as that provision, in conjunction with Article 27.1 and 27.2, provided WTO Members with sufficient flexibilities to modulate their patent protection of biotechnology inventions according to their needs, interests and ethical standards.

78. As one of the co-sponsors of document TN/C/W/52, his delegation had proposed modalities for the three TRIPS-related issues under the Doha Development Agenda, namely GI register, TRIPS/CBD and GI extension. His delegation was committed to that common platform on TRIPS issues and supported their parallel treatment. He welcomed the resumption of the Director-General's consultations on the issues of GI extension and TRIPS/CBD, and indicated that his delegation remained open to amending the TRIPS Agreement to introduce a mandatory disclosure requirement. Indeed, provided the requirement was properly calibrated, it would allow Members to keep track at the global level of all patent applications with regard to genetic resources and associated traditional knowledge, and would help patent examiners establish novelty more accurately and contribute to prevent the misappropriation of genetic resources and associated traditional knowledge.

79. The representative of Colombia said that biodiversity was an opportunity for economic and social development. An approach focusing on the sustainable use of biodiversity should generate tangible benefits for developing countries. The objective was to help overcome poverty while at the same time creating opportunities for new production ventures based on the development of biotechnological know-how.

80. He said that, as a mega-diverse country, Colombia was deeply concerned about the scourge of biopiracy. It therefore closely followed every action at the international level aimed at combating or preventing illegal access to its genetic resources, products derived therefrom and traditional knowledge associated with such resources. This was why Colombia had signed the Nagoya Protocol on 2 February 2011. The Protocol developed the third objective recognized in the CBD, i.e. the fair and equitable sharing of benefits arising out of the utilization of genetic resources and the traditional knowledge associated with such resources. The Protocol sought to provide legal certainty for both the countries of origin and the users of genetic resources or traditional knowledge. The Protocol's provisions that aimed at patent applicants disclosing the origin of genetic resources or associated traditional knowledge and demonstrating that prior informed consent had been secured were necessary for the proper monitoring of genetic resources and traditional knowledge as well as for monitoring compliance with the provisions on access and fair benefit sharing.

81. He said that his delegation had advocated the mutually supportive relationship between the principles enshrined in the CBD and the rules set forth in the TRIPS Agreement in the Council and in other forums where the issue was discussed. In his view, the fact that other Members recognized this relationship in the WTO and in other international organizations was a very positive sign. He hoped that others would acknowledge the reality of the situation and contribute to successful progress in the discussions on this subject in the WTO.

82. The representative of Japan said that the issue of biopiracy should be addressed with a clear distinction between the issue of erroneously granted patents and that of CBD compliance. The Nagoya Protocol provided solutions to the issue of CBD compliance with provisions for the review of their effectiveness. WTO Members should respect those solutions. Discussions on the issue of CBD compliance in other forums would re-negotiate what had been agreed to in the Nagoya Protocol. The priority was the implementation of the Nagoya Protocol. In addition, the Council should take into account the work being conducted in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), especially its intersessional working groups.

83. Turning to the Bolivian proposal, he reiterated his delegation's position that the incentive given by patent systems was critical in the field of biotechnology.

84. The representative of Turkey indicated the importance of having a balanced and comprehensive agreement on the three TRIPS-related issues. He said that those three issues should be treated in parallel as part of the Single Undertaking. He was open to the proposal to amend the TRIPS Agreement in order to introduce disclosure requirements. He said that harmonization between the TRIPS Agreement and the CBD would contribute to the protection of global environment and would prevent the extinction of species and biopiracy.

85. He said that, under the draft Turkish Patent Law, when an invention was based on genetic resources or traditional knowledge, the source of the genetic resource or traditional knowledge had to be disclosed. The details of the disclosure requirement were provided in the implementing regulation, which would enter into force after the adoption of the draft Patent Law.

86. The representative of Ecuador said that, given the complexity and relevance of the Nagoya Protocol to the work in the TRIPS Council, his delegation supported India's suggestion to invite the CBD Secretariat to make a presentation on the Nagoya Protocol in the TRIPS Council. He recalled that more than 80 WTO Members had co-sponsored document IP/C/W/474, which covered their concerns over Article 27.3(b) of the TRIPS Agreement. The incorporation of the principles of prior informed consent, fair and equitable benefit sharing and the disclosure of the sources of genetic resources and associated traditional knowledge into the TRIPS Agreement would effectively prevent biopiracy. Members should also be able to introduce specific provisions on the legal effects of non-compliance with the disclosure requirement.

87. He further said that database systems or contract arrangements were precarious as they did not solve the fundamental problem. An amendment to the TRIPS Agreement to introduce the above-mentioned principles and to introduce the provisions on the legal effect of non-compliance was needed to resolve the problem of misappropriation and biopiracy. Therefore, he said that Members should begin negotiations on the basis of the Director-General's consultations in order to fulfil their mandate provided in the Doha Work Programme.

88. The representative of Chile said that the three agenda items were of high priority to his delegation and that it had participated actively in the Director-General's consultations. Although Chile was not a megadiverse country, it had endemic genetic varieties because of its geographical characteristics. As a party to the CBD, Chile was considering the development of legislation to regulate the use of genetic resources. The Fisheries Research Institute, which was part of a ministry in Chile, was trying to gather data on genetic resources in Chile. The Ministry of Agriculture had the authority to reach contractual agreements and could ensure compliance with the CBD.

89. He said that the divergences on the TRIPS/CBD issue had existed for a long time. Chile was open to exploring the advantages and disadvantages of various options on the table, including contractual arrangements, database systems, and mandatory disclosure requirements, within the framework of the TRIPS Council. However, the artificial linkage between the issues of TRIPS/CBD and GIs would have an effect on that discussion.

90. The representative of Kenya congratulated Maldives on its graduation from the United Nations list of least developed countries. While he thanked Japan for its presentation on the Nagoya Protocol in its capacity as the host country of the Protocol, he said that the presentation should have been made by the CBD Secretariat. He supported the CBD Secretariat's observer status in the TRIPS Council, which would enable Members to seek clarifications on various subject matters of the Nagoya Protocol.

91. He said that the instrument established by the Nagoya Protocol appeared to be voluntary in nature, as seen in its Articles 6 and 17. Besides it was not clear what remedies were available for parties not meeting their obligations. He said that the delegation of Japan was keen to indicate that some countries had requested the establishment of checkpoints, such as intellectual property examination offices and authorities providing regulatory approval of products, and had demanded mandatory disclosure requirements at those checkpoints, but those requests did not get support of other countries. He appreciated the choice of language of "some countries" and "other countries" without clarity on the fractionation of those requesting it and those opposing it.

92. In conclusion, he said that the instrument required to prevent biopiracy and misappropriation of traditional knowledge and folklore was not yet achieved from the perspective of intellectual property, and that mandatory disclosure requirements were a solution which would provide a mechanism to monitor the use of genetic resources, traditional knowledge and folklore for intellectual property rights and therefore to enhance the implementation of prior informed consent and access and

benefit sharing with the owners or custodians of genetic resources and traditional knowledge. Therefore, his delegation supported the proposal of mandatory disclosure requirements.

93. The representative of Switzerland said that biotechnology held great promises for mankind, both the developing and the developed world investment in research and inventive activities in the field of technology should be stimulated through patent rights. Patents protected only the commercial exploitation of inventions for a limited time, after which the invention fell into the public domain. The inventor could either disclose his invention to obtain patent protection or keep it a trade secret. Mere discoveries of something new in the nature were not patentable. In other words, life forms as such could not and must not be patented. Patents should only be granted for new, inventive and non-trivial contribution to the advancement of technology, which required an inventive effort and a considerable resources and investment by the inventor.

94. Article 27.3(b) was a balanced provision providing Members with the necessary degree of flexibility. A non-burdensome disclosure requirement in patent applications relating to the source of genetic resources or traditional knowledge on which the invention was based could contribute meaningfully to enhancing transparency, legal certainty and patent examination standards, including novelty. The disclosure requirement in the TRIPS Agreement could help promote an understanding of the importance and benefits that biotechnology held for mankind and of the role patents could play. Therefore, his delegation had co-sponsored the modalities text contained in document TN/C/W/52. He thanked the Director-General for resuming his consultations on the issues of TRIPS/CBD and GI extension and said that those consultations should not lag behind the general pace of work under the Doha Work Programme.

95. The representative of El Salvador said that, given the importance attached by WIPO to finding a solution for the three agenda items, she welcomed the proposal to invite the representative of WIPO IGC to present a report on its recent activities at the next meeting of the TRIPS Council. Referring to the consultations held by the Director-General, she requested the WTO Secretariat to prepare a written report on the status of those consultations in addition to a verbal report made by the Director-General to the General Council.

96. The representative of Chinese Taipei said that the TRIPS/CBD issue was a critical issue concerning a number of different stakeholders. While there was a need to ensure that the owners of genetic resources and traditional knowledge had a fair and equitable benefit-sharing mechanism, inventors needed an incentive to invent and innovate, which should not be reduced, and the legal certainty of patent systems needed to be preserved without placing undue burden on either patent examiners or patent applicants. All those principles should be considered to evaluate different approaches or proposals. She indicated her delegation's willingness to participate in discussions and consultations in the TRIPS Council.

97. Referring to the Bolivian proposal, she supported Australia's intervention, saying that the flexibilities provided for in Article 27.3(b) allowed Members to implement the patent protection of biotechnology appropriately at domestic level by taking into account their own needs and interests. The review of Article 27.3(b) should not lead to any lowering of the level of patent protection for biotechnological inventions. She did not support the artificial parallelism between the issues of TRIPS/CBD, GI extension and GI register, and said that the attempt to make such a linkage between the three TRIPS issues and to include them jointly as part of the Single Undertaking was not helpful. Each issue should be discussed and considered on its own merits. She urged the Director-General to intensify his open-ended consultations on the two implementation-related issues.

98. The representative of the United States said that parties to the Nagoya Protocol were required to designate a national focal point or authority to make information regarding access procedures available, and in cases where there were multiple competent authorities in a country, to clarify what

each authority's respective responsibility might be. That could assist those who were interested in conducting research to obtain appropriate access without obstruction to their research. Parties who required prior informed consent must provide for legal certainty, clarity and transparency for their domestic requirements and for fair and non-arbitrary rules and procedures on accessing genetic resources. Regulatory predictability was vital for attracting and sustaining research and investment, and for generating benefits to be shared. Clarity and transparency in domestic procedures would also help research to be conducted in a legitimate manner.

99. He noted that there was no patent disclosure requirement in the Nagoya Protocol, which underscored his delegation's view that the shared objectives could be met by the access and benefit-sharing provisions of the Protocol and that there was no need for a patent-related disclosure requirement. Companies, universities and research institutes in the United States were interested to learn whether parties to the CBD planned to adopt the Nagoya Protocol and how they would implement the Protocol. Similarly, since it was governments that would enter into the Protocol, his delegation was interested to learn their views and did not see a need for the CBD Secretariat to present information about implementation by parties.

100. Referring to Bolivia's paper, he associated his delegation with the statements made by the delegations of Korea and Switzerland, saying that a patent could only be granted if three patentability criteria were met.

101. He said that the TRIPS Council had continued to engage in a useful and constructive exchange of views on those issues based on a sharing of national experiences and by posing and responding to questions from Members. The Council could and should continue to work on those issues. His delegation did not support amending the TRIPS Agreement to address the concerns of some Members, and did not think that doing so would be the most effective way to address these concerns. During the Council's meetings in the past, Members had discussed patents and the relationship of intellectual property to the CBD at length. In his view, proposals to mandate the disclosure of the source of genetic resources, prior informed consent and mutually agreed terms would neither improve the patent system, nor promote the shared objective of providing a mechanism to address misappropriation. Such proposals would inject significant uncertainty and unpredictability into a system that was essential to promote the innovation that could solve many of the problems that faced the world.

102. The risks posed to the benefits that flew from innovation were not worth the price, particularly when new patent disclosure requirements would offer so little to promote the shared objectives. The patent examination process was not a suitable mechanism for ensuring compliance with unrelated regulatory requirements. Patent examiners did not review inventors' tax filings, or verify inventors' vehicle permits, or enforce safety rules in the inventors' laboratories. Nor should patent examiners be required to verify the origin of genetic resources.

103. Because of the importance of patents and the need for patent applications to be appropriately searched and examined, Members needed to be careful about what the patent system would be asked to do besides issue quality patents. Asking the patent system to enforce the requirements of another international agreement would result in costlier patents and in increased processing times. Furthermore, asking patent applicants to pay more to file a patent application, and to file more complicated patent applications, would discourage inventors from seeking patent protection, and encourage them to protect the invention as a trade secret, or to avoid commercializing the invention.

104. The role of the patent system was to encourage innovation. Innovation was important to societies to promote public health by finding new treatments and cures for life threatening diseases, new tools to increase energy efficiency as well as disease-resistant plants. The ability to obtain a patent in the United States and many other countries provided an important incentive for universities,

research centres and companies to invest in research to find solutions to the problems that threatened the food supply and the health of our peoples.

105. He said that he recognized that some delegations might believe that the benefits of patent disclosure requirements would outweigh the cost to patent applicants and to society. These delegations suggested that the patent disclosure requirement was merely a transparency tool. Disagreeing with this, he said that his delegation believed that patent disclosure requirements would burden applicants, examiners and society, and would not provide a benefit to the holders of genetic resources.

106. For example, the U.S. Patent No. 2,717,437 was the patent for the hook and loop fastener product known by the Trademark VELCRO. That invention was the work of a Swiss amateur-mountaineer and dog owner, George de Mestral. One day after a hike in the mountains, he and his dog both returned home covered with burrs (plant seed-sacs/genetic resources). Observing the burr clinging to the tiny loops in the fabric of his pants, de Mestral developed hook and loop fasteners. If that patent application had been filed today, would de Mestral have been required to disclose where he had found the burrs?

107. Under the Swiss Patent Law, disclosure was required where the inventor had access to a genetic resource, where the contact was sufficient to identify specific properties relevant to the invention, and where the invention was directly based on the genetic resources or traditional knowledge. In that example, those burs, as seedpods, would likely be considered genetic resources. The inventor had pulled the burs off his pants, and observed hooks on the burrs and loops on his pants, so that would ostensibly qualify as sufficient contact. The inventor had used the properties of the burrs to create hook and loop fasteners. It would seem that disclosure would likely be required under that example but Members should ask themselves why and how would knowing that the burr came from Switzerland help the patent examiner identify prior art or determine whether the invention was patentable. How Switzerland would have actually benefited from the disclosure and what if the source was not clear, for example, where the invention was a mix of, or drew upon knowledge of, many different genetic resources from different countries.

108. The complexity of such disclosures could be staggering. For example, in 1966, a genetic resource had been discovered in one of the US national parks, which led to the invention of polymerase chain reaction (PRC), a common and often indispensible technique used in medical and biological research laboratories. As of February 2011, there had been more than 19,000 U.S. patents relating to PCR. That was only one genetic resource, and the 19,000 plus patents a demonstration of how dispersed knowledge from genetic resources could become. There was no benefit proportional to the cost from such a requirement. Instead, there was a burdensome and unpredictable requirement with which each and every patent applicant and examiner would need to grapple with. Moreover, those requirements were new and untested in many cases, so their full impact on innovative activities around the world had not been evaluated.

109. At a time when people needed innovators to develop inventions to solve the world's problems, they should not make innovations harder to recognize. There were alternatives that could help guard against erroneously granted patents. He endorsed Canada's intervention, saying that databases of traditional knowledge could be improved so that users could search those databases easily, and obtain accurate results. In addition, tools to enable third parties to provide documents to patent examiners and patent work-sharing activities could also help examiners make the appropriate patentability decisions. To address misappropriation, however, solutions needed to be found outside of the patent system. Members were attempting to do that in their national systems and in other forums. A patent system model would provide inadequate disciplines to address the problem of misappropriation.

110. He said that, according to the US universities and companies, the patent disclosure requirements introduced a risk into the patent system that made litigation of patents more expensive and reduced the value of a patent. With reduced patent valuation, universities, research institutions and companies were less able to obtain a revenue stream to fund continued research and development. That meant that they could afford fewer graduate students or employees, and fewer research projects in general. While there was no shortage of disease in the world, it was unfortunate that the research that could be done was only when countries created an environment permitting the research – and not driven by other factors such as where the disease was most prevalent or most likely to become a global problem.

111. The best mechanism for addressing misappropriation, in the view of his delegation, would be to employ a contractual model within a national system with control and benefits retained by the holders of the underlying genetic resources and traditional knowledge. The contract approach encouraged research and development, and created a sustainable economic model. On the other hand, requiring disclosure of the origin of genetic resources added uncertainty to the patent system and was destined to shift resources from researchers to patent attorneys, without improving the patent system, and by putting any benefit sharing agreements at risk.

112. The representative of Norway believed that the relationship between the TRIPS Agreement and the CBD would be enhanced by introducing a mandatory disclosure requirement in the TRIPS Agreement. She recalled that her delegation had introduced a proposal for an amendment of the TRIPS Agreement in June 2006. She welcomed the adoption of the Nagoya Protocol, which provided an important step forward in achieving the third objective of the CBD, namely the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. That would contribute to achieving the other two CBD objectives, conservation of biological diversity and the sustainable use of its components. Introducing the mandatory disclosure requirement in the TRIPS Agreement would represent a significant contribution in enhancing mutual supportiveness of the TRIPS Agreement and the CBD, including the provisions of prior informed consent, benefit sharing, compliance and monitoring in the Nagoya Protocol.

113. The Chairman said that there continued to be a broad diversity of views on whether or not to amend Article 27.3(b). He noted that India had renewed its proposal that the CBD Secretariat be invited to brief the Council on the Nagoya Protocol. El Salvador had proposed to invite the WIPO Secretariat to brief on the work of the IGC, and also requested the Secretariat to prepare a written report on the Director-General's consultations on the outstanding implementation-related issues. He said that he would pass on that request to the Director-General's Office together with various comments.

114. The representative of Nigeria said that his delegation needed time to reflect those proposals, particularly looking at their implications for on-going negotiations.

115. The representative of the United States said that his delegation needed time to reflect on the proposals to invite the CBD Secretariat and the WIPO Secretariat to make presentations in the TRIPS Council and would welcome informal consultations.

116. The Chairman suggested that the Council request the Chair to continue consulting on the earlier suggestion that the CBD Secretariat be invited to brief the Council on the outcome of the Nagoya meeting, as well as on the suggestion that the WIPO Secretariat be invited to brief on the work of the IGC.

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

F. FOLLOW-UP TO THE REVIEW UNDER PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

118. The Chairman recalled that, at its meeting in October 2010, the Council had conducted its annual review of the "Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" ("the Decision"). The record of that discussion had been annexed to the TRIPS Council's report to the General Council (IP/C/57 and Corr.1).

119. As requested by the TRIPS Council, he had held consultations with a number of Members on follow-up to the review, including the question of a workshop and various other proposals. All delegations he had consulted had agreed that the annual review had been very useful and constructive. However, at the same time, many delegations had felt that the discussion had not been fully exhausted. The consultations had confirmed the broad support for following up open questions and outstanding issues at the present meeting. Consequently, the item had been placed on the agenda.

120. In the course of the annual review, a number of delegations had said that they hoped to further share national experiences, and some delegations had referred to some general or specific issues that they wished to explore in greater detail. During his consultations, some delegations had re-confirmed their intention to provide additional information on some of the specific issues that had been identified during the annual review.

121. In light of those consultations, he said that he had requested the Secretariat to prepare a list of issues that Members had identified at the Council's October meeting as requiring further discussion or information so as to help Members prepare for the present follow-up discussion. This list had been faxed to Members on 16 February 2011. It highlighted these issues on the basis of the record of the annual review. However, he said that if there were also some other issues that Members would wish to follow up, they should feel free to address them.

122. The Chairman said that, during his consultations, some delegations had reiterated their proposal for an open-ended workshop involving all the key stakeholders. However, views continued to diverge on this proposal. According to the proponents, now that the Council had had a productive discussion on these matters at its October meeting, such a workshop would allow for information gathering directly from industry and other stakeholders, and would usefully complement the work carried out by the Council.

123. Some other delegations, however, had reiterated that this was a Member-driven process, and underlined that the outstanding issues should first be followed up amongst Members and that an open-ended workshop remained premature at this stage. They had reiterated that the outstanding issues were part of a Member-driven process that had to be followed up amongst Members first.

124. It had also been suggested that the Council could dedicate sufficient time to the next annual review at its October meeting later in the year.

125. The Chairman recalled that, at the previous annual review, the Secretariat had briefed the Council on the procedural requirements of acceptance. In order to further assist Members in drawing up their instruments of acceptance, the Secretariat had promised to make the information, together with a model instrument of acceptance, available in writing. This information was now available on a

new webpage on "How to Accept the Protocol Amending the TRIPS Agreement" ("the Protocol").[4] This could be accessed through the dedicated gateway page on "TRIPS and Public Health".[5]

126. During the annual review, some delegations had expressed an interest in obtaining information on the implementing legislation that a number of Members had already adopted and notified to the Council. In response to this, the Secretariat had created a new webpage compiling national implementing legislation that had been notified to the Council. The webpage listed those Members that had notified their domestic implementation of the Paragraph 6 System ("System"), and provided links to the relevant documentation. This webpage could also be accessed through the dedicated gateway page on "TRIPS and Public Health".[6]

127. Updating Members on the status of acceptances of the Protocol that was done at Geneva on 6 December 2005, he said that, since the Council's meeting in October 2010, Croatia had notified its acceptance of the Protocol on 6 December 2010, followed by Senegal on 18 January 2011 (documents WT/Let/747 and 753, respectively). Thirty-three notifications of acceptance of the Protocol, including from the European Communities, had been received up to that point. The Protocol was to enter into force for the Members that had accepted it upon acceptance of the Protocol by two thirds of the Members. It was open for acceptance by Members until 31 December 2011, or a later date that may be decided by the Ministerial Conference.

128. The representative of Canada expressed her delegation's appreciation for the joint technical symposium that the WTO, WIPO and WHO had organized in February 2011 on Access to Medicines, Patent Information and Freedom to Operate. The symposium had been an informative gathering that had highlighted the fact that access to medicines was a crosscutting issue.

129. She turned to follow-up information on a question that had been raised during the last annual review concerning the Private Member's Bill C-393. It sought to amend Canada's Access to Medicines Regime (CAMR), which constituted the nation's domestic implementation of the System. After having been examined by a parliamentary committee, Bill C-393 was moving to the third and final reading stage of Canada's legislative process. A vote could possibly occur as early as the following week. Out of respect for the parliamentary process, her delegation would refrain from making any comments on the specific elements of the Bill. However, in her Government's view, CAMR worked well in its current form. She recalled that also her delegation had asked a number of questions at the Council's meeting in October 2010 to which responses remained outstanding.

130. The representative of Canada provided an update on Canada's comprehensive strategy to fight disease and improve healthcare worldwide. During the annual review, her delegation had informed the Council of several funding initiatives, including an additional Can$540 million contribution it had made to the Global Fund in September 2010. Since then, it had continued to operationalize the Muskoka Initiative on Maternal, Newborn and Child Health. Canada's Can$1.1 billion in new funding over five years would focus on three key paths. The first was on strengthening health systems to improve service delivery at the local level by training more health workers and expanding access for mothers and children to needed health care facilities and care at the local level. The second focus was on addressing the diseases and illnesses that were the leading causes of mother and child mortality. The third key path focused on improving nutrition by increasing access to healthful, nutritious foods and nutritional supplements that helped reduce mortality. Given that sub-Saharan Africa faced the greatest challenges in addressing maternal and child mortality, 80 per cent of the new Canadian contribution would flow to that region, specifically to Mozambique, Mali, Malawi, Nigeria,

[4] http://www.wto.org/english/tratop_e/trips_e/accept_e.htm
[5] http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm
[6] http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

southern Sudan, Ethiopia, and Tanzania. Additionally, Canada would address gaps in maternal, newborn, and child health in Afghanistan, Haiti, and Bangladesh.

131. In her delegation's view, though the System was a useful tool, it was not a panacea for the complex problem of access to medicines for the world's poor. As pointed out previously, numerous non-trade policy issues were also at play, including infrastructure, human capital, and a myriad of supply chain challenges. These examples illustrated that some issues relating to access to medicines were simply outside the WTO's expertise. However, she agreed with those who asserted that there were trade policy issues impacting on access to medicines. For instance, many Members continued to maintain tariffs on pharmaceutical products, including patient-ready formats. Some of the compounds on which these tariffs were being applied were for the same HIV/AIDS, malaria and tuberculosis medicines that the System sought to make more easily available.

132. The website of an NGO-led initiative, called the Malaria Taxes and Tariffs Advocacy Project (available at http://www.m-tap.org), contained recently-released data indicating that most malaria-endemic countries, where the disease was either the first- or second-leading cause of death, continued to maintain tariffs on anti-malarial commodities, such as bed nets, medicines, insecticides and diagnostic tests. The website also included an interactive tariff map by country, which illustrated that some WTO Members, whose citizens faced the threat of malaria, imposed tariffs, sometimes exceeding 20 per cent, on one or more of the five anti-malarial commodities listed in the report. She said that the decisions taken by Guinea, Kenya, Uganda, Tanzania, Mauritius, and Papua New Guinea to eliminate tariffs on those commodities that help fight malaria deserved recognition. Ultimately, tariffs on medicines were a tax on the sick, and would not even bring any significant fiscal benefit to the countries that applied them. Tariffs translated into higher prices, reduced access, lower treatment coverage, and higher health expenditures that were unlikely to offset what little fiscal revenue they realized. Though she acknowledged that some countries that imposed tariffs also provided waivers, the waivers themselves could create additional costs and lead to delivery delays.

133. The representative of Canada expressed concern that the deadline for Members to accept the Protocol was fast approaching. Members that had not already done so should deposit their instruments of acceptance with the Secretariat as soon as possible before 31 December 2011. She was interested to learn from those Members who had yet to accept the Protocol why they had not done so. The Council could be used as a forum to share individual experiences that could help those who had not yet been able to accept the Protocol to overcome any potential obstacles.

134. The representative of China noted that, although the annual review of the System had not been completed within the Council's dedicated whole-day session last October, substantial contributions by Members had helped to make it one of the most comprehensive and informative annual reviews ever conducted. The remaining issues and questions needed to be addressed at this meeting of the Council.

135. Noting that Members had different views on how to interpret the fact that the System had only been used once, she asked about the potential implications of this limited use. Projections had predicted that the System would be used more frequently in the future given the change in requirements for new medicines to treat diseases, and the implementation of the TRIPS Agreement by Members. In particular, the implementation of full patent protection for pharmaceutical products in India and the approaching expiration of transition periods in LDCs could make it more difficult to procure generic versions of new medicines. Statistics showed that the number of patients being treated for HIV/AIDS in developing countries had increased to 5.2 million in 2010 from 400,000 in 2003. Generic products were available for most of the first line antiretroviral medicines to treat HIV/AIDS, while most of the second line treatments were subject to patent protection in many countries around the world. The switch to second-line antiretroviral medicines would be at least three times more expensive, costing about US$465 per person per year. Citing the report of the UN Special

Rapporteur, which indicated that one third of the world's population did not have access to affordable medicines, she said that the need for new medicines in the developing world would be urgent and even more costly in the future if no measures were taken to remedy this situation. This gave the System an enhanced significance even though it had been rarely used so far.

136. She noted that many Members saw the System as an administratively complex regulatory framework with restrictive requirements and burdensome costs. They felt that further analysis and evidence would be needed to determine whether the System had fulfilled the mandate of the Doha Declaration, i.e. whether it offered an expeditious and effective solution to the public health problems encountered by developing and least developed countries with no or limited domestic pharmaceutical manufacturing capacities. According to other Members, the System could work. The frequency of its use would not be the appropriate metric to measure its effectiveness. The results had to be evaluated. Some Members believed that the issue of access to medicines had been addressed by alternative approaches to compulsory licensing such as voluntary licensing, donation of health products and bulk purchase pricing mechanisms. However, though Members concerned appreciated donations from the developed world, they believed that voluntary licencing was not enough to address the challenging public health issues they faced.

137. The representative of China said that there was widespread agreement that the causes underlying public health and access to medicine issues were broader. Since the System only addressed one specific aspect of it, a holistic and comprehensive approach was therefore required. This could include the financing of research targeting neglected diseases and the development of appropriate pricing and reimbursement policies. Some of these measures could exceed the Council's mandate. She quoted from the WTO Director-General's opening speech at the trilateral symposium on "Access to Medicines: Pricing and Procurement Policies", which had been jointly organized by the WTO, WHO and WIPO in July 2010. On this occasion, he had said that "global public health is a complex puzzle. Getting it right is a teasing challenge, involving effective use of the full set of applicable policy tools. But it is also a practical craft, rather than a theoretical excursion – meaning that we can and should learn from the actual experiences of others in their efforts to create and disseminate needed treatments. The full perspective needs to cover the international trade dimension, but also consider domestic policies and practices, and above all, the evolving state of the actual global disease burden, priority setting for front line treatments, and patterns of production and dissemination of medicines."

138. She said that nobody could deny that patents and international trade were essential elements regarding the interface between public health and access to medicines in developing countries. Some Members had pointed out that patents would often not be the determining factor in the broader issue of access to medicines, stressing that many complex factors hampered access to medicines in developing countries, including suboptimal procurement systems, poor distribution networks for medicines, and the lack of basic infrastructures, hospitals and health care professionals. Systemic problems, such as taxes and tariffs on imported medicines, or the lack of cold chain storage would often be overlooked in discussions at multilateral level. However, while acknowledging that poor national healthcare systems were characteristic of many developing countries, she noted that intellectual property, especially patents, was also an important element in this regard. Given that the TRIPS Council was the competent WTO body overlooking disciplines governing IP-related issues in international trade, and taking into account that intellectual property rights were among the elements that played an important role for access to life-saving medicines, such as second line antiretroviral medicines, the issues related to access to medicines should be addressed by the Council. It was mandated to do so by Ministers at the Doha Ministerial Conference. Whether the System had provided the adequate economic and political incentives to secure investment in production of generic medicines at affordable prices for markets with little or no manufacturing capacity remained an issue, which deserved further examination.

139. In her delegation's view, Article 30 of the TRIPS Agreement constituted an option for developing countries to address public health crises. This was backed by the TRIPS Agreement and paragraph 4 of the Doha Declaration in which Ministers had clearly reaffirmed "… the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement which provide flexibility for this purpose". As discussed many times since the adoption of the Doha Declaration, Article 30 was a flexibility provided for by the Agreement itself, without the need to amend any of its provisions.

140. Noting the broad discussion at the annual review, she called upon Members to agree on the organization of an open-ended workshop on the implementation of the System. This would allow gathering first-hand information, and suggestions could be made directly by the industry. She also encouraged other Members to share information and experiences in addressing public health issues so that the Council could formulate more tangible solutions for common challenges.

141. The representative of India recalled that the System had been agreed after long and intense negotiations. Its objective was to provide an expeditious solution to the problem of countries with insufficient or no manufacturing capacities in the pharmaceutical sector. It was therefore surprising that, after seven years, only limited use had been made of the System. To his delegation's knowledge, in addition to the Rwanda-Canada case, there had only been three instances where efforts had been made to utilize the System. The first had been by Médecins Sans Frontières (MSF), the second by Ghana and the third by Nepal. All three efforts had been abandoned midway, while it had taken about three years to provide medicines to Rwanda. His delegation had shared some details on this during the previous Council meeting. He suggested that other Members concerned or MSF could be asked to provide further details.

142. He considered that the limited use of the System raised serious questions about its effectiveness and efficacy. There was an urgent need to analyze the reasons for this situation. For this purpose, a range of important questions needed to be examined, including cumbersome or time-consuming procedures for granting compulsory licences, the impact of "TRIPS plus" provisions in regional trade agreements on the use of the System, and the role of weaknesses in the domestic regimes of importing Members. While the discussions at the Council's last meeting had been fruitful, most of the questions had been left unanswered. Additional questions on the systemic impact of "TRIPS plus" initiatives had also been raised since these impinged on public health concerns. His delegation was also awaiting responses to questions that Members had presented to the representatives of WIPO and the WHO. There were still some important pieces that were missing from the puzzle. The resultant gaps could only be filled if all stakeholders were involved in the process. He therefore reiterated India's demand for a dedicated workshop open to all relevant stakeholders, including government representatives, pharmaceutical companies, civil society organizations and others, to better understand the reasons behind the limited use of the System.

143. Referring to reports according to which 350 million persons were living with HIV/AIDS in the world of which only 5 million, representing barely 1.5 per cent, were being treated with medicines, the representative of the Bolivarian Republic of Venezuela noted that there was a clear relationship between counterfeit medicines and the excessively high prices of branded medicines. The poor opted for counterfeit medicines since branded medicines were virtually inaccessible for them. This also had a direct causal link with the advent of the TRIPS Agreement, which had made it possible to monopolize medicines. This had led to massive price increases that continued to grow exponentially.

144. The System had been the General Council's attempt to find an alternative that would alleviate the situation. He noted, however, that many countries had not signed the Protocol, and that his delegation would not do so until it felt that the reform would benefit its population. The clearest sign that the System had been ineffective was the paradoxical fact that its most ardent defenders were developed countries, particularly those that produced both branded and generic medicines. The main

reason why the mechanism had not worked was systemic. It had taken Rwanda years to complete its first attempt, while others had been stranded halfway. These experiences had dissuaded others, including Venezuela, from attempting to use the System. He supported the call for an open-ended workshop with the participation of civil society, private companies and other institutions. Such an event would provide a comprehensive overview of the situation. Hearing the viewpoints of other stakeholders would be beneficial for all.

145. The representative of Angola, speaking on behalf of the LDC Group, said that the LDC Group regarded the adoption of the Protocol as an important milestone in efforts to respond to the difficulties experienced by countries with no or insufficient manufacturing capacities. However, only few Members had deposited their instruments of acceptance six years after the adoption of the Protocol. It was therefore important to establish why countries were not coming forward so that corrective measures could be taken. For this purpose, the LDC Group supported the proposal that an open-ended workshop be held on the implementation of the TRIPS amendment. Such a forum could reveal where the impediments to the acceptance process lay, and how they could be removed. Information on how to accept the Protocol should be incorporated into the national and regional technical assistance and capacity building activities undertaken by the Secretariat. He noted that a number of topics for further discussion and information had been prepared through the Chairman's consultative process to facilitate the System's annual review. Sharing experiences would certainly provide clarity on a meaningful use of the System and any obstacles to such use. Information on alternatives would also be valuable to the LDCs.

146. The representative of Japan said that the System should not be considered in isolation, but as part of a broader effort to improve access to medicines. The Symposium on "Access to Medicines: Pricing and Procurement Practices", co-organized by the WHO, WIPO and WTO in July 2010, had noted that other elements apart from intellectual property rights were important for access to medicines. These included procurement practices and high tariffs. It had also been noted that only five per cent of medicines included on the WHO's list of essential medicines were patent-protected.

147. He said that the follow-up to the annual review should focus on specific aspects, in particular concerns of potential importing Members and issues which had been identified as requiring more information but which had not been answered yet. Canada's efforts to share its experience at the previous meeting had provided a good example. The list of issues that had been prepared by the WTO Secretariat would provide important and useful guidance to that extent. As regards the proposal that an open-ended workshop be organized, his delegation regarded this initiative as premature. The Council should first focus on how to make the System work in a practical manner. When discussing access to medicines, it was important to consider other elements apart from the System.

148. The representative of Ecuador recalled that the objective of the System was to provide an expedient and effective solution to the problem of full access to medicines for Members with no or limited production capacity. Council debates from the previous year had enabled Members to go into greater detail about the System, how it worked, and its effectiveness with respect to achieving the set objectives. However, the use of the System had been limited, after being in existence for almost eight years. Therefore, in order to deal with the issues that could affect the effective implementation of the System, it would be necessary to hold a workshop in which all participants, including industry, government and other stakeholders could present their analyses. With respect to the acceptance of the Protocol, his delegation supported the concerns expressed by the delegation of Venezuela. It continued to have serious doubts about proceeding with it, given the System's lack of efficiency and operability.

149. The representative of Brazil said that the Council's objectives were to assess whether the System was an expeditious solution for countries lacking manufacturing capacity, and to address any shortcomings that were impeding the System's effective operation. She reiterated her delegation's

proposal that the adequateness of the economic and political incentives provided by the System to secure investment in the production of generic medicines at affordable prices be analyzed by the Council and other forums. The fact that the System had only been used once was strong evidence for inadequate incentives. The System, as well as other TRIPS flexibilities, was a tool for helping ensure access to medicines at affordable prices. Her delegation was committed to make the necessary changes so that the System could perform the function for which it had been designed. It was time to include other stakeholders in the discussion to better understand why the System was not being used, and to agree on ways to improve it.

150. Access to medicines at affordable prices was particularly important in Brazil given that its constitution guaranteed free and universal access to healthcare for all citizens. Under Brazil's HIV/AIDS programme, all persons living with HIV/AIDS were entitled to receive free treatment. This included individual health exams, as well as the supply of medicines to treat HIV/AIDS and other opportunistic diseases. 210,000 patients were under treatment for HIV/AIDS in her country, with the number increasing by 30,000 annually. The estimated cost for the HIV/AIDS programme for 2011 was US$500 million, which meant an annual cost per patient of US$2,500. Advances in drug development had provided more effective treatment resulting in significant gains in patients' longevity. This was an important achievement, but it also entailed increased costs. As patients developed resistance, more research and investment would be needed to develop the next generation of drugs, which would come at a higher cost.

151. Her Government had found a balance between the rights granted to IP holders and the interests of society as a whole. Fifty-seven per cent of Brazil's HIV/AIDS patients used second and third generation antiretroviral drugs. The use of these newer generations of drugs increased annually as the life expectancy of HIV/AIDS patients in Brazil had grown from 58 months in 1995 to 108 months in 2007. In order to maintain the sustainability of the programme, Brazil had continuously negotiated with drug makers to reduce the price of antiretrovirals and had made full use of the flexibilities under the TRIPS Agreement. One example had been the issuance of a compulsory licence for the antiretroviral drug Efavirenz in 2007. This was one of the most commonly used medicines in antiretroviral therapy. In 2007, 38 per cent of Brazilian patients had been using it. Because of the growing number of patients and the use of newer generation drugs, the costs of Efavirenz had been jeopardizing the HIV/AIDS programme. At US$ 1.59 a dose, the costs for the Government had amounted to approximately US$ 42.9 million, or US$ 580 per patient, per year. As a result of the compulsory licence, the cost per dose had been reduced to US$ 0.43 a dose.

152. The representative of Peru noted that a workshop open to all stakeholders would enable Members, international organizations, the civil society and the pharmaceutical industry to express their views and to share experiences on both the challenges and opportunities that could be realized through the implementation of the System. His delegation therefore supported the proposal made by the delegations of India, Brazil, China and others to hold such a workshop in the course of 2011. Although the System had been established to ensure that developing countries had access to generic medicines they could not produce domestically, it had only been used once since its establishment. During the last annual review, Members had exchanged views with respect to its use. This enriching dialogue had enabled Members to look at problems and existing difficulties. Some experiences had been positive while others had been less so.

153. The representative of the European Union recalled the importance of input from Members that had experience in implementing the System and called upon them, in particular potential importing countries, to share more information and experiences.

154. In response to the list of issues for further discussion or information, which had been circulated by the Chairman in order to prepare for the follow-up to the annual review, he first addressed the issue regarding developed countries' efforts to transfer technology to least developed

countries, in particular how they had implemented paragraph 7 of the Decision. His delegation had put in place several programmes to provide incentives for technology transfer. The details could be found in the annual reports on technology transfer, which summarized the incentive programmes put in place by the European Union as a whole, as well as by individual member States. Measures taken included the promotion of specific projects, such as direct investment, licensing, franchising, subcontracting, joint research projects, training and technology, management and production methods and capacity building.

155. With respect to the measures taken to ensure the safety and efficacy of medicines manufactured under compulsory licences for export, Regulation (EC) No. 816/2006 had established a system whereby approval would be granted on either the basis of a scientific opinion from the European Medicines Agency in consultation with the WHO, or by a national sanitary authority. This assessment would be based on the same standards and criteria as for medicines intended for domestic use. The standards and criteria offered the highest level of protection adopted by the relevant international organizations.

156. Turning to the question of whether the economic and political incentives provided by the System were adequate to secure investment in the production of generic medicines at affordable prices, he said that the political impetus to provide such incentives lay with the WTO membership. The European Union had put in place implementing legislation, according to which compulsory licences could be granted by the competent national authorities, provided that the applications fulfilled the conditions with respect to the eligible importing countries and that no agreement could be reached with the right holder. Verifying the fulfilment of those conditions and monitoring the use of the System was necessary to ensure that it was not abused for purposes other than public health. No further conditions or restrictions had been introduced in the EU implementing legislation. On the contrary, the latter had even been made accessible to poor countries which were no WTO Members. Packaging and labelling requirements were not excessively costly, cumbersome or difficult to put into practice. Those measures were justified for transparency and compliance purposes.

157. In his delegation's view, the requirements of the System were not responsible for the limited number of applications made to date. They provided the necessary framework for ensuring the proper use of the System. He recalled the existence of many other channels for access to medicines, including seeking voluntary licences or taking advantage of patents on several medicines that had either expired or would expire in the coming years. The additional details provided by the delegation of Canada with respect to the supply of generic medicines to Rwanda by Apotex showed that procedures could be swift. Approval had been given in less than six months through a special review stream, instead of the standard one year period. The problems encountered may be specific to the case at hand. It was premature to conclude from there that the System had failed to serve the objective of enhancing access to medicines without fully analyzing the difficulties. On the contrary, prices had been lowered in the end due to harsh competition by other generic suppliers on the market in Rwanda. Economic incentives may have been low, but to date, it had not been proven that there was any need for such incentives. The System could not be criticized for its limited use if other alternatives were operating well enough to restrain the need to recur to it. Nevertheless, further information and reflection on concrete cases would be valuable to better understand the issue in its broader context.

158. Referring to the Chairman's list of issues, i.e. the question whether TRIPS-plus provision such as data exclusivity had adverse effects on the right to access to medicines, the representative of the European Union noted that, in most cases, the term of data exclusivity did not extend beyond the lifetime of patents. In any event, under EU Regulation (EC) No. 816/2006, data exclusivity did not apply to cases where a compulsory licence had been granted. Therefore, it did not constitute an obstacle to the export of medicines under the System.

159. Addressing the question of what incentives Members had for accepting the Protocol and implementing the System, he said that each WTO Member was responsible for undertaking those acts. Numerous exporting countries had accepted and implemented the Protocol, while others may have been observing how it worked in practice before doing so. Any particular difficulties that importing countries were facing should be resolved through international cooperation and technical assistance. It was therefore important that both sides communicated their needs and expectations.

160. Taking up the issue on the Chairman's list regarding the budget available to actors from the private and public sectors with respect to the distribution of essential medicines, he said that some figures on projects and programmes initiated by the European Union in developing countries had already been provided at the Council's last meeting. Recipient countries would be in a better position to provide further information on how the budget had been used.

161. He finally addressed the issue of how international organizations, such as the WTO and WIPO, could better use their resources for technical co-operation to implement TRIPS flexibilities in collaboration with other organizations including UNCTAD, WHO and UNAIDS. A strong network of cooperation already existed and appeared to function properly. Several events had been jointly organized by the aforementioned organizations. This included the symposia that had been hosted by the WTO, WIPO and WHO in Geneva in June 2010 and February 2011. His delegation would nevertheless welcome any additional initiatives or suggestions since there was always room for improvement in technical cooperation. Further information on experiences acquired to date, particularly by importing countries, on their needs and on the technical obstacles they had encountered, would be helpful in this regard.

162. The representative of the United States referred to the productive exchange among Members during the last annual review. However, more input was still needed from the potential users of the System about their experiences and considerations. As reflected in the Chairman's list of issues of 16 February 2011, there were a number of questions that had been asked but had been left unanswered by delegations, particularly those from potential importing countries. In response to the question about technology transfer to least developed countries, his delegation had provided several examples at the Council's last meeting, which were reflected in the minutes (IP/C/M/64, paras. 260, 262 to 264). Efforts to transfer technology, as well as reflections to further promote such transfer, were on-going. Technology transfer was, however, not merely about licensing of patents. Many pharmaceutical companies had decided not to seek patents in LDCs anymore. As a result, though no patent rights existed to be licensed in these cases, technology was still being transferred.

163. With regard to the safety and efficacy of medicines procured under the System, the US had already provided details on a 2004 policy initiative wherein a US Food and Drug Administration review could be used to streamline the process through which a generic antiretroviral could be added to the WHO pre-qualification list. This would help to ensure that medicines procured under the System were safe and effective, without requiring a separate review by the importing Member.

164. As the delegation of Canada had explained with respect to tariffs, the Abuja Declaration of the Africa Summit on Roll Back Malaria had already recognized in 2000 that domestic taxes and import tariffs were an obstacle to access to bed nets, anti-malarial medicines, insecticides used in indoor residual spraying, and rapid diagnostic tests necessary to fight malaria. They made the tools to fight and treat malaria less available to the poor. There were also a significant number of open questions regarding potential importing Members' experiences, as well as of those Members that had reported their attempts to use the System. For the Council's review to be effective, his delegation supported calls for developing countries to report on their considerations and experiences in evaluating whether and how to use the System. Given that the System had been developed by Members, for Members, it was not clear how it could be assessed without such experiences. His

delegation therefore looked forward to continuing working within the Council and did not see a need to depart from its procedures.

165. The representative of Canada said that the delegation of India and other delegations had made a factual error in referencing a multi-year process for the export of generic medicines to Rwanda. As his delegation had noted at the last annual review and at previous meetings, reference to a three-year period was simply not correct. The process of utilizing CAMR had been operationalized and successfully completed in a matter of months. If there had been extended delays beyond that, those had not been due to the functioning of CAMR, but to other factors beyond the scope of his Government. He referred Members to the facts as set out at previous meetings and reflected in the respective minutes.

166. He reiterated the call on other Members for answers to the questions his delegation had asked at the previous annual review. The current meeting had been characterized as a follow-up meeting. Canada had provided follow-up responses to matters that had arisen in October 2010, but the questions that it had asked, recorded in paragraphs 121, 143, 273 and 274 of the minutes, were left unanswered. Perspectives of Members were the biggest missing piece. Echoing the delegations of the European Union and the United States, he noted that the Council had received little information on experiences with the System from potential importers, or those who had at least explored this possibility.

167. His delegation had, for example, referred to the role of states, in particular as regards tariffs. Governments, not the private sector, were responsible for such tariffs which were directly relevant for access to affordable medicines. He asked the Indian delegation why India imposed tariffs on all five commodities implicated in the fight against malaria, and how this helped its efforts to combat malaria. This question was of direct relevance to the work of the Council and the WTO. While his delegation had not foreclosed on the possibility of a workshop, it was evident that the real gaps lay in the sharing of experiences of states and of information on the policies they exercised. Those had a direct impact on access to affordable medicines.

168. The representative of Kenya informed the Council that his delegation was in the process of accepting the Protocol. The instrument of acceptance would soon be deposited. This was in line with the new constitution of 4 August 2010, which had affirmed the right to healthcare for all citizens. The use of the System could boost the Government's efforts of meeting its obligations on health and IPRs under the new constitution. He supported the proposal for an open-ended workshop, which would provide an opportunity for sharing and exchanging ideas, information and experiences amongst stakeholders. It would facilitate an enhanced use of the System as envisaged during the highly volatile negotiations that had led to its adoption.

169. The representative of Switzerland said that, during the previous annual review as well as in the current discussion on the System, the delegations that had made interventions were either potential exporting countries, or countries with considerable domestic pharmaceutical manufacturing capacity. Those were not the Members for which the System had been established. Potential beneficiary Members with no or limited manufacturing capacity in the pharmaceutical sector therefore needed to voice their concerns and to set out the problems they may have faced in their attempts to use the System. Only on the basis of their experience could the Council evaluate the System with respect to its workability, expeditiousness, and whether other stakeholders should participate in the Council's future review discussions.

170. He noted that the delegate of India had referred to a number of cases where potential beneficiary countries, such as Ghana and Nepal, had started but had later abandoned the drug procurement process under the System. The delegate of India had stated that more information on these cases could be received from those countries in an open-ended workshop on the System.

However, this information should be shared in the Council's discussion as part the annual review. This would allow the Council to consider follow-up steps for the next annual review. The Chairman's list of issues for further discussion or information following the last annual review constituted a useful basis for a well-structured discussion. Many of the issues pertained to potential beneficiary countries under the System. In order to have a meaningful review, it would be important to have input from those countries.

171. He continued by sharing information on a number of issues on the Chairman's list. First, with respect to the transfer of technology, his delegation had submitted its report on the implementation of Article 66.2 TRIPS (IP/C/W/551/Add.2). In particular, paragraphs 28 and 29 pertained to capacity building in the public health and pharmaceutical sectors.

172. Regarding measures taken by potential exporting Members to ensure the safety and efficacy of medicines procured under the System, he reported that the Swiss implementing legislation provided that, when a compulsory licence was granted under the System, a manufacturing authorization had to be obtained according to Article 5, paragraph 1 of the federal drug law (HMG). Recognized standards for good manufacturing also had to be respected (Article 7 HMG). For finished pharmaceutical products, an additional authorization under Article 18, paragraph 1(b) HMG would have to be sought from the Swiss Agency for Therapeutic Products (Swissmedic). The licensee was, however, not required to obtain marketing approval for a product manufactured under the licence, as would be the case under Article 9 of the HMG if marketing was intended in Switzerland. The motivation for this dispense was to make the procedure as expeditious as possible, and to give the beneficiary country the choice of applying its own safety standards and marketing approval procedures. However, the beneficiary country had the option of mandating a specialized external organization to carry out its required safety tests. In Switzerland, this could be done by the Swiss Agency for Therapeutic Products upon receiving a request from the beneficiary country. With regard to test data protection, his delegation concurred with the European Union that this should not pose any problems in cases of licences granted under the System.

173. With respect to incentives for Members to implement the System, the representative of Switzerland said that greater efforts would be required from potential exporting countries than from potential beneficiary countries. Exporting countries needed to amend their national legislation to provide for grants of Paragraph 6-type licences. They also had to establish the associated procedures and safeguards as required by the System. On the other hand, potential beneficiary countries were primarily required to provide reasonable measures proportionate to their administrative capacities in order to prevent diversion of the imported pharmaceutical products from their domestic to third country markets. This would, in any event, be in the interest of a beneficiary country which faced a public health problem and therefore sought recourse to the System.

174. Regarding incentives for the acceptance of the Protocol, it was only coherent for Members to expeditiously proceed with their domestic procedures. The System had been adopted after four years of long and difficult negotiations. It was a unanimously adopted solution to an issue that had been deemed to be of pressing importance at the time. Each Member now had to take the necessary steps to accept and effectively implement the multilateral decision at the national level. It was therefore surprising to learn that the delegations of Venezuela and Ecuador were planning to deposit their respective instrument of acceptance only after having been convinced that the mechanism would have positive benefits for them.

175. He recalled the Chairman's opening remarks in which he had reported that 33 Members, including the European Communities, had deposited their instruments of acceptance of the Protocol. This meant that another 42 Members were needed to accept the amendment before it could enter into force by the deadline of end of 2011. He urged Members that had not yet accepted the Protocol to undertake the necessary steps to do so without further delay.

176. In reaction to Canada's allegation that tariffs were impeding access to medicines, the representative of India referenced WHO figures, according to which the average wholesale price of medicines had fallen to 60 per cent of the branded medicines price after expiry of the patent in the United States. This finding concerned a market segment with just one generic competitor, whereas prices had fallen to 29 per cent of the branded price in case of ten competitors. Another study of the US market had also found that the prices of generic medicines had decreased with the number of competitors in the market. A study of the French Agence nationale de la recherche had drawn similar conclusions for some developing country markets. Upon exploring determinants of anti-retroviral medicine prices in Brazil and 13 African countries, it had found that the introduction of generic competition remained an essential factor for lowering prices even after controlling of other relevant factors.

177. The representative of the Bolivarian Republic of Venezuela reiterated the need for an open workshop to provide constructive feedback to developing countries and potential importers. This would not be easy given that nothing of that nature had been tried before. As the example of Rwanda had shown, it had taken years to successfully complete the process. Others had abandoned their efforts halfway. But efforts had to persist. This explained his delegation's concern about committing to a process that would likely be difficult and complicated. Therefore, doubts about the System needed to be addressed before committing to it.

178. The representative of Ecuador said that it was the sovereign decision of each Member to ratify an agreement. The experience to date indicated that the System did not work. This was evident from the fact that despite being established in August 2003, there were no other experiences beyond those that had already been discussed. He asked the Swiss delegation what its real interests in the System were given that it had one of the largest pharmaceutical industries in the world, what programmes it had created to deal with public health in developing countries, and what its interests were in preventing the convening of a workshop.

179. In support of the delegation of India, the representative of Brazil provided an example to illustrate the impact of patent rights on prices. In Brazil, Abacavir was an important medicine to treat HIV/AIDS patients. In 2007, the drug had cost US$2.1 per dose. When the patent had expired in 2008, the cost of the drug had fallen to US$0.88, i.e. a reduction of almost 60 per cent.

180. The representative of the Secretariat noted that on the occasion of the enhanced annual review of the System at the Council's last meeting, the Secretariat had provided a detailed overview of the technical co-operation efforts it had undertaken in relation to public health and access to medicines. In a brief update to supplement that report, he said that public health as well as the TRIPS provisions that were most relevant to innovation and access to medicines continued to form an integral part of the Secretariat's technical assistance efforts. This emphasis on public health had strengthened since the adoption of the Doha Declaration. Since the TRIPS waiver in 2003 and the Protocol Amending the TRIPS Agreement in 2005, virtually all technical cooperation activities concerning TRIPS had addressed the System. These had included regional workshops, Geneva-based events, national seminars, or other more tailored activities. This amounted to a large number of activities that were very diverse in character.

181. He said that three general trends in technical cooperation had been identified in October. The first was the increasing trend towards partnerships with other organizations, both within and beyond the established trilateral partnership between the Secretariats of the WHO, WIPO and the WTO. This trend was occurring at the planning, coordination and programme delivery levels, so as to ensure that the necessary breadth of expertise was available, and to more effectively leverage the investment of resources. The second trend was towards providing a stronger practical understanding of the relevant elements of the TRIPS Agreement and how they could be practically embedded into operational procurement programmes with greater interconnection between the technical cooperation activities

and those responsible for the procurement of medicines. The third trend was towards exploring the possibilities arising from the enhanced and more integrated information basis that was emerging, including on patent coverage, prices and access to medicines by vulnerable populations. This strong base of information was enabling technical cooperation to become more focused, tailored and practically oriented towards specific drug procurement objectives.

182. Those trends had been consolidated since the previous Council meeting. On the first point, cooperation with other international organizations in the conduct of such technical assistance had been further enhanced. Efforts to coordinate and provide mutual support for the programme partners had increased. Following the Doha Declaration and the establishment of the System, the WHO had become a regular participant in all regional and Geneva-based activities to the extent that resource constraints had permitted. It had thus joined WIPO as the WTO Secretariat's traditional partner, and had brought a vital public health perspective to each of the programmes. In addition, others concerned with access to medicines, including civil society, public sector procurement initiatives, industry representatives, public private partnerships, and policy analysts, had also been closely involved. Events such as the Colloquium for Teachers and the Advanced Course had included presentations from participating scholars and policy analysts from a wide range of countries. Many of these participants had chosen to address access to medicines and related issues in their presentations.

183. He said that the increased focus on technical cooperation in relation to public health and intellectual property had been assisted through active dialogue, coordination and partnership with the WHO and WIPO. Such highly productive collaboration had facilitated the further involvement of WHO and WIPO experts in WTO technical cooperation activities. This had enabled more effective and tailored technical cooperation efforts that were subsequently being conducted from a better informed factual background. Earlier in the year, a regional seminar had taken up this issue. The "WTO Regional Workshop on Intellectual Property and Public Policy for Central and Eastern European and Central Asian Countries" had benefited from the valued contributions of colleagues from WIPO, and experts from both the WHO headquarters in Geneva and from its regional office responsible for Europe.

184. He said that the trilateral cooperation had also led to joint technical cooperation activities, including technical symposia co-organized by the three Secretariats. A report on the "Access to Medicines: Pricing and Procurement Practices" symposium, held in Geneva on 16 July 2010, had already been provided at the Council's last meeting. The symposium had laid out several themes for continuing cooperation with respect to the exchange of empirical data and practical experience. As a follow up to that activity, the three Secretariats had jointly organized a second symposium on 18 February 2011. Hosted by the WHO, the event had taken up one of the specific themes covered in the inaugural symposium, namely "Access to Medicines, Patent Information and Freedom to Operate". To strengthen the technical basis of discussions, the symposium had been preceded by a WIPO-hosted workshop on 17 February 2011 on "Patent Searches and Freedom to Operate".

185. The objectives of the most recent symposium had been (i) to highlight the importance of easy access to patent information for providing access to medicines, (ii) to show how patent information could be used in determining the freedom to operate for improving access to medicines, (iii) to explore what kind of patent information would be required for this purpose, (iv) to explore to what extent this information was available and accessible, and (v) to identify information gaps that needed to be addressed. The symposium had focused on new research outcomes and data that could provide an empirical and practical basis for discussion. Speakers had described several projects aimed at deriving a better understanding of access to medicines issues through the enhanced use of patent information tools. Various providers and users of intellectual property information had shared their perspectives. These had included representatives from research-based industries, procurement initiatives, the generic pharmaceutical industry, and information providers such as national patent offices. At a strictly technical level, this had been a capacity building event and not a policy forum.

For this reason, there had been no specific conclusions or outcomes. However, it was worth noting that the symposium had included a vigorous and insightful discussion covering the challenges of access and making use of patent information to build a clearer overview of freedom to operate issues pertaining to product development and access to medicines. The symposium had concluded with a note of cautious optimism about the potential for an improved and more geographically representative coverage of patent information. Full details would be posted on the websites of the three organizations so that the material could be used to support continuing dialogue and technical cooperation in this field.

186. The resources that were being developed to support technical cooperation included the table of legislation implementing the System. The table had been created and posted on the WTO website in response to specific requests made at the previous Council meeting. There had also been other material developed subsequent to the previous October's discussion. The material would help Members understand the necessary steps and practical implications of accepting the Protocol. It had been presented on the basis of the discussions and background explanations provided at the previous Council meeting. The material addressed the frequently asked questions in this subject area, and provided a model form for acceptance of the TRIPS Amendment. It also made some important practical points. In particular, it distinguished between the act of acceptance of the TRIPS Amendment and the implementation of the System. On the one hand, acceptance could be described as a means of confirming on the international plane that other Members were entitled to use this flexibility. On the other hand, a choice whether or not to use the system was a separate matter, in the domain of domestic implementation, including through necessary legislation. Members were already entitled to make use of the System even in advance of the amendment coming into force.

187. The representative of the WHO provided further information on two questions featuring on the Chairman's list of issues. The first concerned an analysis of how international organizations such as the WTO and WIPO could better utilize their technical cooperation resources to implement TRIPS flexibilities through their collaboration with other organizations, including UNCTAD, WHO and UNAIDS. Since the adoption of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the WHO, WTO and WIPO had intensified their collaboration on all issues regarding public health and intellectual property. The three Secretariats were meeting monthly to coordinate their current activities and to discuss future joint efforts in the fields of training and capacity building, technical assistance and educational activities, which included collaboration with the WIPO Academy. This collaboration avoided duplication through parallel programmes. Instead, it allowed each organization to bring its specific strengths and expertise in jointly designed programmes. This had led to better designed programmes and greater efficiency in programme development and delivery.

188. The second comment related to the request that the WHO prepare a detailed report on the coverage of TRIPS flexibilities in its technical assistance activities. He said that further information on this issue would be included in his Organization's next report on technical cooperation activities, due to be circulated ahead of the Council's meeting in October. In advance of the forthcoming report, two recent joint activities would merit a brief presentation. Following the first WHO, WIPO and WTO symposium on "Access to Medicines: Pricing and Procurement Practices", the three organizations had organized another trilateral technical symposium on "Access to Medicines, Patent Information and Freedom to Operate" at the WHO on 18 February 2011. It had focused on the growing importance of patent information for public health, especially in the areas of procurement of medicines, technology transfer and freedom to operate strategies. The challenge of locating relevant and up-to-date information on the patent status of key essential health products had been highlighted. This was often a highly complicated undertaking, particularly for people that were not trained in this area. The meeting had thus confirmed that there was a need to facilitate access to this information, and to help procurement officers and other health officials in finding and interpreting it according to their needs. In collaboration with WIPO and the WTO, the WHO would continue to work to make

patent information more accessible and understandable to people from the health sector. The programme of the symposium, a background paper, and all presentations could be found on the websites of the three organizations. Webcasts of all presentations and discussions would also be made available online.

189. Furthermore, with regard to the issue of the implementation of TRIPS flexibilities, an upcoming joint UNAIDS, WHO and UNDP Policy Brief on "Using TRIPS Flexibilities to Improve Access to HIV Treatment" would review how countries could use and had used those flexibilities to increase access to HIV treatment. The policy brief would be published later in March.

190. Referring to the Chairman's list of issues, the representative of WIPO addressed the request to it to provide "information on projects under its Development Agenda, covering the development dimension with respect to the effective use and implementation of TRIPS flexibilities". The Development Agenda (DA), which had been agreed by the member States of WIPO in 2007, contained 45 recommendations to enhance the development dimension of the Organization's activities. Key were recommendations 13, 14, 17, 22 and 25, which focused on enhancing the understanding and use of flexibilities in the intellectual property system. In November 2009, the Fourth Session of the Committee on Development and Intellectual Property (CDIP) had discussed recommendation 14, and it had requested WIPO to prepare a document on flexibilities in the area of patents. At the Fifth Session of the CDIP in April 2010, the Committee had discussed a preliminary document on "Patent-Related Flexibilities in the Multilateral Framework and their Legislative Implementation at National and Regional Levels" (CDIP/5/4). It had requested the Secretariat to review the document to reflect Members' comments and to include new flexibilities, and to propose a work programme on flexibilities for consideration by the Committee. Such a future work programme on flexibilities in the IP system had been agreed at the Sixth Session of the CDIP in November 2010 (based on document CDIP/6/10). It covered work in the area of patents, stocktaking of WIPO's activities relating to flexibilities in the IP system, and technical assistance in the use of such flexibilities.

191. She reported that the CDIP had agreed on a range of activities with respect to flexibilities. The first activity included work on five new patent-related flexibilities. Those included WIPO's continuation of work on transitional periods, patentability of substances existing in nature, disclosure-related flexibilities, ex-officio IP office control of contractual anticompetitive clauses, and examination systems. This work was being undertaken by WIPO's Innovation and Technology Sector: Patents and Innovation Division. The CDIP had also agreed that WIPO should organize national and regional seminars for the exchange of practical experiences in the implementation of flexibilities. In this context, a regional seminar on the effective implementation and use of several patent-related flexibilities would be organized by the Innovation and Technology Sector in Bangkok in March 2011. The Deputy Director General of WIPO's Development Sector had drawn the CDIP’s request to the attention of other non-patent-related areas at WIPO, with the view of organizing further seminars and workshops to address other fields of IP.

192. She said that it had also been agreed that information on flexibilities be integrated into WIPO's technical assistance activities, legislative advice and capacity-building activities. This was bearing in mind that Recommendation 1 of the DA provided that such assistance would be "inter alia, development oriented" and demand-driven. The Deputy Director General of the Development Sector had informed all WIPO divisions involved in technical assistance initiatives that the CDIP decisions were a confirmation of WIPO's engagement in the area. Furthermore, the CDIP had also agreed on the creation of a webpage that would be dedicated to the use of flexibilities. Located on WIPO's website, the webpage would contain a roadmap indicating the areas of WIPO's work relating to the flexibilities, as well as links to relevant sectors. The page would also provide materials and output from WIPO seminars, workshops and technical assistance activities dealing with the flexibilities. A "resources" section would provide links to studies on flexibilities produced by WIPO, and by

WIPO-commissioned experts, as well as to relevant materials produced by other intergovernmental organizations.

193. Finally, the CDIP had agreed upon the creation of a database accessible from the aforementioned webpage. This would allow users to access relevant provisions on flexibilities in national IP laws, as well as information on national experiences and case studies in implementing the flexibilities. The DA Coordination Division and WIPO's IT Sector were undertaking preparations for the database.

194. The representative of WIPO recalled that, taking into account the DA as well as the broader context of the United Nations' Millennium Development Goals, her Organization had established its programme on Intellectual Property and Global Challenges. Through this programme, WIPO, as the specialized United Nations agency responsible for intellectual property, endeavoured to lead the international policy dialogue on the intersection between intellectual property and global public policy issues, in particular as regards global health, climate change, and food security. The focus on these three subject areas had been guided largely by member states' requests, inter alia, in the DA, since the most immediate impact of many of these global problems was borne by developing and least developed countries. WIPO was actively cooperating with diverse international partners, particularly within the United Nations system, in order to contribute to shared solutions for those challenges.

195. She concluded by noting that public health was a central issue. WIPO had engaged in the clarification of pertinent issues underlying health innovation and access to medicines. The trilateral cooperation between the WHO, WIPO and the WTO had been established and was working well. Hopefully, it would contribute to the enhancement of the empirical and factual information bases for policy makers, and would support them in addressing intellectual property issues in relation to global policy themes such as public health.

196. The representative of the United States welcomed the webpage detailing how to accept the TRIPS amendment. He hoped that it would assist Members in accepting the Protocol so that the Council's objective of getting the amendment passed could be achieved.

197. The Chairman said that there was no consensus on any further follow-up to the annual review or on the preparations for the Council's next annual review in October, including whether, and if so how and when, to hold an open-ended workshop, or how to approach the requests for further information as listed in the annex to the fax he had sent to Members and Observers on 16 February 2011. He suggested that his successor be requested to consult with Members on any further follow-up and on preparations for the next annual review.

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

G. NON-VIOLATION AND SITUATION COMPLAINTS

199. The Chairman recalled that, at the Seventh Session of the Ministerial Conference, Ministers had directed the TRIPS Council to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to their next Session. It was agreed that, in the meantime, Members would not initiate such complaints under the TRIPS Agreement. The eighth Ministerial Conference would be held in Geneva on 15-17 December 2011. At its meeting in March 2010, the TRIPS Council had agreed to keep the item on non-violation and situation complaints on the agenda as a regular item so as to allow Members who would have new thinking to share it, and also enable the Council to revert to the question of the further organization of its work in the light of any future suggestions.

200. The representative of the United States said that, in the past, WTO Members had agreed to extend the moratorium on non-violation and situation complaints. That had been a significant concession on the part of the United States, as the moratorium had been set to expire at the Sixth Ministerial Conference. His delegation nonetheless maintained that non-violation complaints were fully appropriate in the context of the TRIPS Agreement. The views of the United States were well known in that regard, as reflected in document IP/C/W/194. The possibility of non-violation disputes had been a part of the GATT dispute settlement system since the beginning. The TRIPS Agreement had been carefully negotiated to accommodate different legal regimes and to accommodate Members' need to achieve policy objectives. The availability of non-violation complaints would merely assist Members in their efforts to preserve the balance of concessions and to protect against measures that frustrate legitimate expectations. Accordingly, the United States was of the view that the moratorium should expire at end of the upcoming Ministerial Conference.

201. The representative of the Bolivarian Republic of Venezuela believed that non-violation and situation complaints could not be dealt with under the TRIPS Agreement and requested that the moratorium continue until the issue had been fully resolved.

202. The representative of China said that, since the TRIPS Agreement was quite different from GATT in nature and structure, she believed that application of non-violation and situation complaints to the TRIPS Agreement was unnecessary and would raise fundamental concerns and limit the use of flexibilities. She suggested that the next Ministerial Conference either suspended the application of non-violation and situation complaints under the TRIPS Agreement or decide on an unlimited moratorium until Members decided otherwise.

203. The representative of Nigeria, speaking on behalf of the African Group, endorsed the views of Venezuela and China. He said that the next Ministerial Conference should agree that non-violation and situation complaints are inapplicable or, alternatively, grant an indefinite moratorium to provide more certainty for Members planning their health policies.

204. The representative of Switzerland said that his delegation continued to take the view that non-violation complaints were applicable in the context of the TRIPS Agreement, the same way that they were applicable to GATT and GATS. The TRIPS Agreement had been concluded to achieve and obtain – across the markets of all WTO Members – minimum standards for the protection of IPRs. Those minimum standards, agreed and implemented into national law, improved market access. From that perspective, the TRIPS Agreement did not differ from GATT or from GATS. All three agreements were aimed at improving market access; they were market access agreements. The wording in Article 64.2 and 64.3 of the TRIPS Agreement was clear in that non-violation complaints would not apply under the TRIPS Agreement after the moratorium would have expired at the next Ministerial Conference.

205. The Chairman said that the Council was to provide its recommendations to the Ministerial Conference at its end-of-year meeting in October. In case any delegations had any ideas to share, he encouraged them to do so as soon as possible so as to allow the Council sufficient time to consider them.

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

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

207. No statements were made under this agenda item.

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

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

209. The Chairman recalled that Article 24.2 provided that the Council shall keep under review the application of the provisions of the GI Section of the Agreement. He recalled that, at its meeting in March 2010, the Council had agreed to encourage Members to share information on and notify bilateral agreements related to the protection of geographical indications, which they had entered into, to the Council. He therefore encouraged any Member that was party to any such bilateral agreement and had not yet shared such information with the Council to do so. He also invited those delegations that had not yet provided responses to the Checklist of Questions contained in document IP/C/13 and Add.1 to do so. Also those Members that had already provided responses could provide updates to the extent there had been any significant changes to the way they provided protection to geographical indications.

210. The Council took note of the information and agreed to revert to the matter at its next meeting.

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

211. The Chairman recalled that, at its last meeting, the Council had taken up its eighth annual review of developed country Members' reports on their implementation of Article 66.2 of the TRIPS Agreement. In concluding that item, he had indicated that he would provide delegations an opportunity at the present meeting to make further comments on the information submitted for that meeting that they had not yet been able to study.

212. The representative of Bangladesh, speaking on behalf of the LDC Group, said that there had been notable progress in the format and contents of reports submitted under the Article 66.2 review. However, there was still room for further improvement to ensure that the process was not just about fulfilling notification obligations, but about having tangible results in terms of promoting and encouraging technology transfer to LDC Members in order to enable them to create a sound and viable technological base. He thanked the WTO Secretariat for convening the eighth annual review, in line with the decision by the Ministers in Doha, Qatar in 2001, calling upon Members to put in place a mechanism for ensuring the monitoring and the full implementation of the Article 66.2 obligations. He recalled that paragraph 1 of the decision of the TRIPS Council of 19 February 2003 called upon developed country Members to submit annually reports on action taken and planned in pursuant of their commitments under Article 66.2. To this end, they shall provide new detailed reports every third year and, in the intervening years provide updates to their most recent reports. Those reports shall be submitted prior to the last Council meeting scheduled for the year in question.

213. The purpose of the review was threefold: first, to provide Members an opportunity to pose questions in relation to the information submitted and request additional information; second, to discuss the effectiveness of the incentives provided in promoting and encouraging technology transfer to LDC Members in order to enable them to create a sound and viable technological base; and third, to consider any points relating to the operation of the reporting procedure established by the Decision. He thanked those developed countries that had provided the pulse to the TRIPS Council on incentives they had provided to their enterprises and institutions in their territories with a view to promoting and encouraging transfer of technology to LDCs in order to enable them to create a sound and viable technological base.

214. Article 66.2 contained an obligation for developed country Members. This obligation was specific to LDCs and was about providing incentives to enterprises and institutions in developed country Members territories. The purpose was to promote and encourage the transfer of technology;

the ultimate objective was to enable LDCs to create a sound and viable technological base. That effort should be the basis for measuring the effectiveness of incentives provided to LDCs. In order to ensure quality reporting, there was a need for the Council to begin deliberating on critical elements with a view to developing a common understanding of the contents of the reports. He said that the LDC Group had identified two critical areas in relation to the Article 66.2 obligations: the definition of technology transfer and illustrations of the type of incentives.

215. As regards the definition of technology transfer, it was clear from the reports that had so far been submitted that there was a lack of common understanding of what constituted technological transfer. Hence the inclusion in some reports of technical cooperation activities. It would be useful to provide a non-exhaustive list of what could possibly be regarded as technology transfer for the purposes of Article 66.2.

216. Regarding the type of incentives, it would equally be important to have a non-exhaustive list to guide the reports. It would also be useful to have showcases, and to hold brainstorming sessions on specific examples of incentives that had led to transfer of technology and subsequent contribution to the building of a sound and viable technology base in LDCs.

217. In order to draw best practices, there was a need to ensure that the reports were LDC-specific and that incentives resulting in transfer of technology were distinct from technical cooperation activities provided under Article 67. The reports should also provide an indication of funding or budget allocated for staff incentive programmes and follow a harmonized format. To this end, he reiterated the proposal that the Council identify clear parameters on the nature of technology transfer and on the types of incentives provided by developed countries to their enterprises and the institutions. To this end the LDC Group had circulated a possible template that could be considered. He looked forward to receiving remarks on that. It would also be useful to work towards having a toolkit for assessing the impact of technology transfer.

218. The Council took note of statements made.

K. TECHNICAL COOPERATION AND CAPACITY BUILDING

219. The Chairman recalled that, at its last meeting, the Council had taken up its annual review of technical cooperation. Given that some information from Members and other intergovernmental organizations were made available only a short time before the review, he had indicated that he would offer a further opportunity to make comments on that material. Since that meeting, the Council had received additional information from the African Regional Intellectual Property Organization (ARIPO) (IP/C/W/549/Add.6).

220. As regards notifications of contact points for technical cooperation on TRIPS, since the Council meeting in October, updates to contact points notified earlier had been received from the European Union and Korea.

221. As regards LDC needs assessments, he recalled that paragraph 2 of the TRIPS Council's 2005 decision on the "Extension of the Transition Period under Article 66.1 for Least-Developed Country Members" provided that "with a view to facilitating targeted technical and financial cooperation programmes, all the least-developed country Members will provide to the Council for TRIPS, preferably by the 1 January 2008, as much information as possible on their individual priority needs for technical and financial cooperation in order to assist them taking steps necessary to implement the TRIPS Agreement". To date, such information had been received from five Members, namely Sierra Leone, Uganda, Bangladesh, Rwanda and Tanzania. At the Council's last meeting, Rwanda had complemented its earlier needs assessment with the proposed Rwanda Development and IP Capacity Building Project which intended to translate the needs assessment identified into a concrete technical

assistance project (IP/C/W/548/Add.1). The needs assessment of Tanzania had also been presented to the Council's last meeting (IP/C/W/552).

222. He urged those least-developed country Members that had not yet provided information on their individual priority needs for technical and financial cooperation to do so.

223. The Council took note of the information provided and agreed to revert to the matter at its next meeting.

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

224. The Chairman recalled that, at its past five meetings, the Council had had on its agenda the letter from the Chair of the General Council concerning ways to improve the timeliness and completeness of notifications and other information flows in the area of its responsibility. In order to facilitate the Council's consideration of this issue, the Secretariat had presented to the October 2009 meeting a factual background note IP/C/W/543 it had prepared at the Council's request that summarized the relevant procedures and provided information on the use of these procedures, as well as contained suggestions on how to improve the transparency and user-friendliness of the notification system. Furthermore, the Secretariat had orally reported on further developments in this area. Those delegations that had spoken on this issue had supported the suggestions contained in that note to improve the transparency of the system, and had encouraged the Secretariat to pursue this task. At its last meeting, the Council had agreed to revert to this agenda item at the present meeting so as to provide Members a further opportunity to share any comments they might have on the matter, and also to allow the Secretariat to inform the Council on any further enhancements to its services improving the transparency and user-friendliness of the notification system.

225. The representative of the Secretariat said that the basis of the work in this area remained the framework for notifications established by the decisions of the Council. The specific steps to improve the timeliness and completeness of notifications and other information flows, in response to the letter from the Chair of the General Council, had proceeded in the light of the document commissioned by this Council (IP/C/W/543), and the Council's review of that document. Significant progress had been made in improving the transparency and user-friendliness of the notification system, but much work still needed to be done. So far, some key steps included the establishment of a joint portal for notification, created with the indispensable cooperation and support of WIPO; the implementation of a Members' transparency toolkit; and the incorporation of notified materials and notification procedures into technical cooperation activities.

226. Document IP/C/W/543 had reported a very high rate of coverage of laws provided in initial notifications to the Council, but a more mixed record for subsequent notifications of new laws and amendments introduced since the original notification had been made. The improved system for providing notifications, including the implementation of the portal and incorporation of that element into regular technical cooperation activities, seemed to have helped Members in updating their notifications, and had simplified and streamlined the flow of documentation, especially since the WIPO-WTO common portal became fully operational.

227. The most recent development had been the presentation of the two contact point lists established under Articles 67 and 69 in the form of a drop down list, to make that valuable practical information more accessible than the paper based format which had been difficult to access and to use in a routine manner. That was a small, but significant, step towards the stated objective of making the remarkable body of valuable practical information that was embedded in 15 years of notifications more readily accessible and therefore put more systematically to use to serve the beneficial purpose

for which it was designed. He said that he was hopeful that when he would report back to the Council under the Chairman's successor, he would have further practical steps to outline.

228. The Chairman suggested that the Council agree to revert to this agenda item at its next meeting so as to provide Members a further opportunity to share any comments they might have on the matter, and also to allow the Secretariat to inform the Council of any further enhancements to its services improving the transparency and user-friendliness of the notification system.

229. The Council took note of statements made and so agreed.

M. INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

230. The Chairman recalled that, under this agenda item, information had usually been provided in relation to new accessions to the WTO and developments in the area of dispute settlement, as well as about acceptances of the recent TRIPS amendment. He said that he had already provided information on acceptances of the TRIPS amendment under item F, and on this occasion he had no other new developments to report in these areas.

N. OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

231. The Chairman said that the list of 15 pending requests for observer status in the TRIPS Council by other intergovernmental organizations was contained in document IP/C/W/52/Rev.12. Although the Council had recently made some progress on two requests, it had not been able to reach consensus on the other requests. At its last meeting, the Council had requested him to continue his consultations on the matter. These had focused on the two issues that the Council had discussed at its last meeting, namely the suggestion that the CBD Secretariat be invited to the Council's meetings on an ad hoc meeting-by-meeting basis; and the suggestion that the ad hoc meeting-by-meeting invitations to the secretariats of ARIPO and OAPI be converted into a permanent observer status. Unfortunately, he was not in a position to report any new thinking in respect to those issues.

232. The representative of Brazil said that her delegation was in favour of all pending requests for observer status, but there was one particular case, the CBD request, which had been presented a long time before. She could not understand why the observer status of the CBD had been denied by one delegation.

233. The representative of Bangladesh, speaking on behalf of the LDC Group, endorsed the views of Brazil. He considered that the same treatment offered to ARIPO and OAPI should be applied to other organizations and suggested to grant them observer status on an ad hoc meeting-by-meeting basis until the Council agreed on criteria to apply.

234. The representative of Ecuador endorsed the views of Brazil and Bangladesh and reiterated his view that the CBD Secretariat should be recognized as an observer, at least on an on-going basis until permanent status could be granted.

235. The representative of India said that his delegation supported the statements made by Brazil, Bangladesh and Ecuador. There was a strong linkage between TRIPS and CBD and therefore the presence of the CBD Secretariat in the TRIPS Council would be a great benefit to WTO Members. He therefore strongly supported the CBD request.

236. The representative of Angola endorsed the position of the LDC Group and other countries. The treatment granted on a meeting-by-meeting basis to ARIPO and OAPI should be extended to the CBD. He recalled that there was a pending issue in the Council relating to the relationship between

the TRIPS Agreement and the CBD. The Council should remain a technical body and he considered particularly useful to give an opportunity to the CBD Secretariat to make comments.

237. The representative of China supported the views expressed regarding the pending requests. The relevance of the CBD Secretariat to the Council was obvious and she did not see any substantial reason to oppose the observer status of the CBD Secretariat. It should be granted observer status at least on an ad hoc basis.

238. The representative of Peru endorsed the views of Brazil, Bangladesh, India and China. The 15 applications made by various organizations were of equal importance. They could make a significant contribution to the work of the Council. However, the application made by the CBD Secretariat was particularly relevant. His delegation did not see any reason why the CBD could not participate on an ad hoc basis. Its participation would be quite valuable. The CBD was very important in terms of intellectual property. It would be very useful for all Members to have first-hand information which could be provided by the CBD Secretariat with respect to the system used in that forum. He therefore supported the request made by the CBD Secretariat to achieve an observer status on an ad hoc basis. He appealed to Members for flexibility and understanding.

239. The representative of Indonesia said that the adoption of the CBD Nagoya Protocol had made it more relevant for the Council to discuss the relationship between the TRIPS Agreement and the CBD. He believed that it was high time to grant observer status to the CBD Secretariat as this organization was quite relevant to discussions in the Council. Allowing the CBD Secretariat to take part in the Council's meetings would not impair but rather enrich the discussions and widen the Council's perspective.

240. The representative of Nigeria, speaking on behalf of the African Group, supported the admission of the CBD Secretariat as an observer on a meeting-by-meeting basis. He also reiterated his position that the two TRIPS implementing bodies in Africa, i.e. ARIPO and OAPI, should be granted a permanent observer status. He did not see any reason why such a decision would not be adopted right away.

241. The representative of Kenya endorsed the statement made by Nigeria on behalf of the African Group. The CBD Secretariat should be granted observer status and the two African regional IP organizations should be graduated from ad hoc observers to permanent status since all of them had a useful role to play in the Council. That notwithstanding, he did not have any problem with the admission, as observers, of all the organizations listed in document IP/C/W/52/Rev.12.

242. The representative of Zimbabwe joined those who had advocated for the admission of the CBD Secretariat on an ad hoc basis. He also supported the position of the African Group regarding ARIPO and OAPI.

243. The representative of the United States said that he had no objection to granting permanent observer status to ARIPO and OAPI. He said that he would refer the views expressed concerning the CBD Secretariat to capital. However, he could not join the Members seeking to include the CBD as an observer either on a permanent or on an ad hoc basis at that time.

244. The representative of Egypt said that his delegation's position was well known. He welcomed OAPI and ARIPO as ad hoc observers on a meeting-by-meeting basis. All pending requests should be dealt with equally.

245. The Chairman said that the Council seemed unable to achieve consensus on either of the two specific proposals that had been made. He therefore suggested that that his successor continue informal consultation on these points.

246. The representative of Brazil said that, for clarification, he wished to know if there were any objections, apart from the United States to the CBD case, to the granting of observer status on a case-by-case, meeting-by-meeting basis to other organizations. He understood that the delegation of Egypt would like to see other delegations also being granted a permanent observer status.

247. The representative of Egypt said that he welcomed giving OAPI and ARIPO ad hoc observer status on a meeting-by-meeting basis. All the other organizations should be dealt with on the same basis as OAPI and ARIPO. After that, the Council could discuss giving permanent observer status to all the organizations.

248. The representative of Nigeria, speaking on behalf of the African Group, thanked the United States for its favourable response to the request by ARIPO and OAPI. He also urged Members to look at document IP/C/W/549/Add.6, which gave a clear indication of the activities being undertaken by ARIPO. He suggested that the Chair continue consultations to see if consensus could be reached.

249. The Chairman suggested that the Chair consult on the issue of observer status for international intergovernmental organizations. He said that the consultations could cover an ad hoc observer status for the CBD, a permanent observer status for ARIPO and OAPI, and the consideration of ad hoc meeting-by-meeting observer status for other organizations on the list.

250. The Council took note of statements made and so agreed.

O. OTHER BUSINESS

251. The Chairman recalled that, at its meeting in June 2010, the Council had agreed to grant an ad hoc observer status on a meeting-to-meeting basis to the African Regional Intellectual Property Organization and the African Intellectual Property Organization. He suggested that the Council again invite ARIPO and OAPI to attend the Council's next formal meeting on an ad hoc basis.

252. The Council so agreed.

P. ELECTION OF THE CHAIRPERSON

253. The Chairman recalled that, at its meeting of 22 February 2011, the General Council had noted the consensus on a slate of names of chairpersons for WTO bodies. On the basis of the understanding reached, he proposed that the Council for TRIPS elect H.E. Mr Federico A. González from Paraguay as its Chairperson for the coming year by acclamation.

254. The Council so agreed.

ANNEX

At the request by the delegation of Canada, the text it submitted at the Director-General's informal consultations on 17 February 2011 is reproduced below.

MISAPPROPRIATION OF GENETIC RESOURCES

There is no universally accepted definition for the concept of misappropriation of genetic resources (GR); this is also true in Canada. A patent application contains claims outlining the subject matter for which protection is being sought, a description which teaches the invention and optionally drawings and/or sequence listings, depending if they are required for the disclosure of the invention. Patent applications concerning an invention which includes biological material has additional requirements for the description. A deposit, as of the filing date, of a sample of biological material associated with the invention may, in some, but not all cases, be required for the description to sufficiently disclose the invention.

Patent applications can be submitted electronically or in hard copy. An applicant must request an examination within five years of filing a patent application. Once a request for examination is filed (and the associated fee is paid), the application is transferred to the examiner who is the expert in the field of the subject matter. Examiners review the claims, description and drawings to verify they conform to the Patent Act and Rules. A search is carried out to identify any relevant prior art (generally, written documentation that shows that what is being claimed is not novel or obvious). The application is examined in view of the criteria of novelty, obviousness, support, utility, patentable subject matter, and general compliance with the Canadian Patent Act and Rules and jurisprudence.

Canada has no specific government-level rules for patents for inventions based on genetic resources and associated traditional knowledge (TK). There are, also, no specific patent practices for the processing of applications involving genetic resources and traditional knowledge. However, under section 34 of the Patent Act and as further provided for in chapter 18 of the Canadian Intellectual Property Office's (CIPO) Manual of Patent Office Practice, any person may file prior art with the Commissioner of Patents, and protest against the granting of a patent. Any prior art material so submitted becomes part of the file of the application.

Patent applications involving genetic resources are treated by the same process and assessed using the same criteria as any other patent application. In Canada, there are no distinct or specialized approaches for search and examination of inventions based on genetic resources and associated traditional knowledge. Furthermore, Canadian patent examiners do not necessarily concentrate or restrict their searches to particular areas of technology, but rather tailor their searches to suit the subject matter covered by the patent application. The success of these searches has more to do with the availability of prior art sources and databases than with disclosure of the source country.

Of note, the focus on greater access for IP offices to digital libraries of genetic resources such as India's Traditional Knowledge Digital Library (TKDL) has proved to be a practical way of protecting GR and TK within the patent system. Having greater database access helps examiners in determining what is traditional knowledge, however, any references obtained from these sources must be able to be made available to the applicant in order for them to be citable under Canadian Patent

Law (i.e., secret information can not be used as a bar to patentability). The selection of the database for a given search is the decision of the examiner. CIPO notifies the Council of Scientific & Industrial Research (CSIR), the TKDL provider, of the number of times documents from the database are cited by examiners as prior art. The Canadian Patent Act allows for third-party protests and submissions of prior art. Prior art submissions from TKDL, as with any other public database, are acceptable under these provisions.

The current system by which different types of patents are categorized and classified does not allow for patents to be identified according to whether they contain a claim to genetic or biological material. Furthermore, there are no means for an examiner to verify whether the source or origin of material, as identified by the applicant, is accurate.

Since genetic resources do not stop at national borders, limiting prior art searches to any given source country would be counterproductive and may overlook relevant prior sources located in other countries. Rather, Canadian patent examiners perform broader searches according to the subject matter; chapter 17 of the Manual of Patent Office Practice provides comprehensive guidelines on biotechnology, including as regards novelty.