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Council for Trade-Related Aspects of Intellectual Property Rights

ANNUAL REVIEW OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Report to the General Council

1. Paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 (the "2003 Decision") provides that the Council for TRIPS shall review annually the functioning of the System set out in the Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review is deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

2. The Council for TRIPS undertook the seventh annual review in October 2010. The General Council took note of the report of the Council for TRIPS (IP/C/57 and Corr.1) at its meeting on 14 December 2010 (WT/GC/M/129, paragraph 90). The present report covers the period since October 2010.

3. At its meeting on 1 March 2011, the Council for TRIPS followed up a set of questions that remained open and outstanding issues that arose at the seventh annual review. It also addressed the preparations for the eighth annual review at its meeting on 7 June 2011. At its meeting of 24-25 October 2011, the Council undertook the eighth annual review. Annex 1 to this report records the statements made in the review.

4. The paragraphs below set out factual information regarding the implementation and use of the 2003 Decision, discussions on the operation of the System and the acceptance of the Protocol Amending the TRIPS Agreement.

1. Information on implementation and use of the System established under the Decision

5. Since the last annual review, the Republic of Korea has notified its Patent Act and Presidential Decree No. 23306 of 26 July 2010 on "Provisions Regarding the Expropriation and Implementation of the Patent Right". They provide the legal basis for the Republic of Korea to act as an exporting Member, as well as an importing Member in situations of national emergency or other circumstances of extreme urgency.[1] China has submitted its "Revised Rules for the Implementation of the Patent Law 2010"[2], which complements its earlier notification of the amended Patent Law. As of 30 September 2011, 12 Members, including the European Union (formerly the European Communities), have thus formally notified the Council for TRIPS of the changes made to their domestic legal regime in order to implement the 2003 Decision. An overview of the notified implementing laws and regulations, including hyperlinks to the legal texts, is available on a dedicated page on the WTO website at http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

[1] IP/N/1/KOR/P/4.
[2] IP/N/1/CHN/P/3.

6. During the period covered by the present report, no notifications by importing or exporting Members pursuant to paragraphs 1(b), 2(a) and 2(c) of the 2003 Decision have been made to the Council for TRIPS. As foreseen in the 2003 Decision, the Secretariat regularly updates a page on the WTO website dedicated to this Decision, notably to ensure the public availability of notifications made pursuant to it (http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm).

2. Discussion on the operation of the System established under the Decision

7. As requested by the Council for TRIPS at its annual review in October 2010, the Chair held small group consultations on the follow-up to the review on 7 and 15 February 2011. At these consultations, all delegations shared the view that the seventh annual review had been very useful and constructive. However, at the same time, many delegations felt that the discussion had not yet been fully exhausted. Given the broad support for following up open questions and outstanding issues, the item was put on the agenda of the Council's meeting on 1 March 2011. In advance of the meeting, the Chair faxed to Members a list of issues, both general and specific, that Members had identified at the annual review in October 2010 as requiring further discussion or information, so as to help delegations to prepare for the follow-up discussion.

8. At the meeting in March 2011 (IP/C/M/65, paragraphs 128-179), Members' expressed their readiness to share experiences on the use of the System and to continue practical fact-based discussions in order to have a full understanding of its functioning. In response to a question raised in the annual review in October 2010, the delegation of Canada shared further information on the review of Canada's Access to Medicines Regime and provided an update of its comprehensive strategy to fight diseases and improve healthcare worldwide. A number of other delegations provided information in response to the general or specific issues on the list relevant to them, including on incentives for technology transfer and on ways in which they ensured the safety and efficacy of medicines manufactured under compulsory licence for export. The Secretariats of the WTO, WHO and WIPO provided further information on their technical co-operation programmes, including their trilateral co-operation activities.

9. As to the operation and review of the System, some delegations reiterated their concern that the System had only been used once since 2003 and that it had taken some three years to deliver the medicines to Rwanda in this context. They also noted that only a limited number of Members had accepted the Protocol Amending the TRIPS Agreement. Some other delegations noted that the System was a useful tool and that its limited use so far was not an appropriate measure of its success. In their view, the use so far had demonstrated that the System could work effectively and that it could play a supportive role in the wider effort to improve access to essential medicines, which depended on numerous trade and non-trade policy issues. It was also noted that there could be a need to use the System more frequently in the future, in particular given the introduction of product patent protection for pharmaceutical products in developing country Members and the expiration of transition periods for least-developed country Members.

10. While agreeing that annual reviews constituted a good platform for sharing experiences and evaluating the operation of the System, some delegations reiterated their proposal to complement them by a dedicated workshop to allow for an in-depth study of any potential obstacles to the System's effective and expeditious operation. In order to gather information on all aspects and concerns, the workshop should be open to all relevant stakeholders. Some other delegations maintained that the review of the functioning of the System was a Member-driven process. They reiterated their invitation to potential importers and beneficiaries of the System to report on their experience, positive or negative, with the System directly to the Council, considering that holding an open-ended workshop would be premature. The Council requested the incoming Chair to continue consultations on any further follow-up and on preparations of the next annual review.

11. In addition, the Chair drew the Council's attention to two new pages on the WTO website providing information on:

(a) implementing legislation notified by a number of Members to the Council;[3] and

(b) procedures for accepting the Protocol, including a model instrument of acceptance[4].

At the Council's meeting on 7 June 2011, the Chair recalled this information on the procedural requirements for acceptance and clarified that it was not necessary for a Member to introduce domestic implementing legislation before accepting the amendment to the TRIPS Agreement as an additional flexibility that other Members may choose to make use of.

12. At the Council's meeting in June 2011, the Chair reported under "Other Business" on the small group consultations he had held. Delegations reiterated their positions regarding the format of future work in this area. The Chair indicated that it was his intention to pursue further consultations on the preparation for the eighth annual review and the issue of a possible workshop. He suggested that the Council work on the assumption that the annual review would at least follow a similar approach to that which had been widely welcomed by delegations in October 2010, noting his intention to continue consultations with Members on possible ways of improving and preparing for the review (IP/C/M/66, paragraphs 249-265).

13. At the meetings in March and June 2011, many delegations expressed their appreciation of the trilateral symposia that the WHO, WIPO and the WTO had organized on issues connected with public health and intellectual property, which had provided useful background information on a complex subject matter that could serve Members' respective constituencies, and underscored the sources of practical experience and empirical data that can help support policy debates.

3. Decision on the Amendment to the TRIPS Agreement

14. As called for in paragraph 11 of the 2003 Decision, the General Council adopted a Protocol Amending the TRIPS Agreement, by a Decision of 6 December 2005 (WT/L/641). The Protocol is open for acceptance by Members until 31 December 2011 or such later date as may be decided by the Ministerial Conference (WT/L/785). In accordance with Article X:3 of the WTO Agreement, the Protocol will enter into force upon acceptance by two thirds of the WTO Members.

15. As of 21 October 2011, the following Members have notified their acceptance:

- United States, 17 December 2005, WT/Let/506;
- Switzerland, 13 September 2006, WT/Let/547;
- El Salvador, 19 September 2006, WT/Let/548;
- Republic of Korea, 24 January 2007, WT/Let/558;
- Norway, 5 February 2007, WT/Let/563;
- India, 26 March 2007, WT/Let/572;
- Philippines, 30 March 2007, WT/Let/573;

[3] http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.
[4] http://www.wto.org/english/tratop_e/trips_e/accept_e.htm.

- Israel, 10 August 2007, WT/Let/582;
- Japan, 31 August 2007, WT/Let/592;
- Australia, 12 September 2007, WT/Let/593;
- Singapore, 28 September 2007, WT/Let/594;
- Hong Kong, China, 27 November 2007, WT/Let/606;
- China, People's Republic of, 28 November 2007, WT/Let/607;
- European Union (formerly the European Communities)[5], 30 November 2007, WT/Let/608;
- Mauritius, 16 April 2008, WT/Let/619;
- Egypt, 18 April 2008, WT/Let/617;
- Mexico, 23 May 2008, WT/Let/620;
- Jordan, 6 August 2008,WT/Let/630;
- Brazil, 13 November 2008, WT/Let/636;
- Morocco, 2 December 2008, WT/Let/638;
- Albania, 28 January 2009, WT/Let/639;
- Macao, China, 16 June 2009, WT/Let/645;
- Canada, 16 June 2009, WT/Let/646;
- Bahrain, 4 August 2009, WT/Let/652;
- Colombia, 7 August 2009, WT/Let/650;

[5] The text of the instrument of acceptance reads as follows:

"THE PRESIDENT OF THE COUNCIL OF THE EUROPEAN UNION,

HAVING regard to the Treaty establishing the European Community, and in particular Article 133(5) in conjunction with the first sentence of the first subparagraph of Article 300(2) and the second subparagraph of Article 300(3) thereof,

NOTIFIES by these presents the acceptance, by the European Community, of the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005,

CONFIRMS, in accordance with Article 300(7) of the Treaty establishing the European Community, that the Protocol will be binding on the Member States of the European Union.

The Secretary-General/High Representative — The President of the Council of the European Union"

- Zambia, 10 August 2009, WT/Let/651;
- Nicaragua, 25 January 2010, WT/Let/663;
- Pakistan, 8 February 2010, WT/Let/664;
- Former Yugoslav Republic of Macedonia, 16 March 2010, WT/Let/671;
- Uganda, 12 July 2010, WT/Let/684;
- Mongolia, 17 September 2010, WT/Let/684;
- Croatia, 6 December 2010, WT/Let/747;
- Senegal, 18 January 2011, WT/Let/753;
- Bangladesh, 15 March 2011, WT/Let/758;
- Argentina, 20 October 2011, WT/Let/830;
- Indonesia, 20 October 2011, WT/Let/831;
- New Zealand, 21 October 2011, WT/Let/832; and
- Cambodia, 1 November 2011,WT/Let/833.[6]

16. At the Council's meeting on 1 March 2011, the delegation of Kenya informed the Council that it was in the process of accepting the Protocol and that the instrument of acceptance would soon be deposited. Nigeria reported to the Council's meeting on 7 June 2011 that Members of the African Group were making efforts in order to proceed with the acceptance of the Protocol.

17. Information on the status of acceptances of the Protocol is periodically updated in revisions of document IP/C/W/490.

18. Given the present status of acceptances, and the indications that a number of Members are actively progressing their acceptance of the Protocol, the Council for TRIPS submits the attached proposal to the General Council for a decision to extend the period for acceptances of the Protocol. A draft of such a proposal for consideration by the Council is contained in Annex 2 of this document.

[6] *Secretariat note*: Cambodia's instrument of acceptance has been received after approval of the present report at the Council's meeting on 24-25 October 2011. It has been added in order to ensure that the list of WTO Members who have notified their acceptance is up-to-date.

ANNEX 1

Excerpt from the Minutes of the Council's meeting of 24-25 October 2011
to be circulated as IP/C/M/67[1]

G. REVIEW UNDER PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

1. The Chairman said that, as requested by the Council, he had held consultations with a number of Members on how best to structure the Council's discussions in order to make the review as useful as possible. In light of these consultations, he had faxed to the Members a list of topics and issues for discussion on 14 October 2011. The list merged the list of six topics for discussion prepared for the System's annual review at the Council's meeting in October 2010 with the list of issues for further discussion or information identified by Members which the then Chairman had faxed to Members in February 2011 to guide the discussion on the follow-up to the annual review at the Council's meeting in March. While the Chairman clarified that while this approach was based on the structure and content of the 2010 review and represented a natural continuation of what was well received at that time, it was not necessarily exhaustive. Members should therefore feel free to raise any additional issues during the review.

2. He 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 that proposal. The last topic on the list, namely "Next steps and recommendations", would enable the Council to continue the discussion of this point.

3. Regarding the purpose of the TRIPS Council's annual review and the report to the General Council, he said that paragraph 8 of the waiver Decision provided that the Council would annually review the functioning of the System set out in the Decision with a view to ensuring its effective operation and annually report on its operation to the General Council. Such a review would be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

4. The Secretariat had circulated a draft cover note for the Council's report modelled on previous years' reports (JOB/IP/4). It contained factual information on the implementation and use of the System established under the Decision, discussions regarding its operation, and the status of acceptances of the Protocol Amending the TRIPS Agreement. In accordance with the way that the Council had prepared its reports in previous years, the part of the minutes of the meeting that reflected the discussions held under the agenda item could be attached to the cover note.

5. The Secretariat had also circulated an update to the note on the status of acceptances of the Protocol that the Council had requested it to prepare at its meeting in October 2006 (IP/C/W/490/Rev.8). Since the circulation of that document, Argentina and Indonesia had deposited their instruments of acceptance on 20 October, and New Zealand had deposited its instrument on 21 October (WT/Let/830, 831 and 832, respectively). 37 notifications of acceptance of the Protocol, including from the European Union (formerly the European Communities), had thus been received. He reminded Members that the Protocol would enter into force for the Members concerned when it had been accepted by two thirds of the Members.

6. Turning to the consolidated list of topics and questions for discussion in the annual review, the Chairman said that this list combined the list of topics for discussion that had been prepared for the October 2010 review and the list of issues for further discussion or information identified by

[1] The paragraph numbering of this excerpt will not correspond with that of the minutes of the TRIPS Council meeting but has been included for the convenience of users.

Members that had been prepared to guide the follow-up discussion at the Council's meeting in March 2011. The follow-up questions were grouped under the appropriate headings. The footnotes indicated the delegations that had posed those follow-up questions and the further information that had already been provided in response to those questions at the Council's meeting in March. Therefore, there was no need to repeat or duplicate what had already been said on the record. He said that structuring the discussion this way should help the Council carry out the review with most continuity on the basis already established, and thus ensure a productive and useful discussion of the System that would help Members better understand the Paragraph 6 System's operation and any concerns related to it.

1. Experience of Members who have used or considered using the Paragraph 6 System
2. Implementation of the System into domestic legislative and regulatory framework

7. The representative of Canada said that her delegation had provided extensive information on its experience at the last annual review of the Paragraph 6 System in October 2010. She updated Members on the status of Bill C-393, which had sought to amend Canada's Access to Medicines Regime (CAMR). It had died on the Order Paper at the end of the last parliamentary session before the May 2011 general federal elections in Canada. No similar bill had yet been introduced in the new session of Parliament.

8. She recalled that her delegation had asked a number of questions at the Council's meeting in October 2010, to which responses remained outstanding. The Paragraph 6 System, while a useful tool, should not be viewed as a panacea for the complex problem of ensuring access to medicines. The impact of intellectual property rights on access to medicines, in particular on their price and on healthcare as a whole, had to be viewed as commensurate with the role of intellectual property alongside other factors that affected the price and availability of medicines. Those factors included infrastructure, rational use of medicines, health systems, and tariffs on medicines and related commodities that merely taxed the sick.

9. The Paragraph 6 System should therefore not be viewed as the only solution - which it was not, and had never been intended to be - but rather as a mechanism that sought to modulate one of the factors, i.e. intellectual property rights, which affected the price of medicines. She recalled the genesis of the Paragraph 6 System, wherein Ministers had recognized the need for the TRIPS Agreement to be part of the "wider national and international action" that addressed grave public health problems such as HIV/AIDS, malaria and tuberculosis. The difficult negotiations that had ensued resulted in a mechanism that had not been designed to be a tool to lower medicines prices generally, but rather to help address acute public health crises.

10. She therefore urged Members to focus their efforts on ensuring that the Paragraph 6 System worked as it had been intended to and called on all Members that had not already done so to deposit their instruments of acceptance of the Protocol Amending the TRIPS Agreement. Innovative financing mechanisms, such as pooled procurement and voluntary licensing, should be welcomed. Key issues such as the need for prevention strategies and rational medicine use, the strengthening of health systems, and the training of health workers should also be addressed by WTO Members in the WTO and other multilateral fora, such as the WHO, as well as bilaterally.

11. The representative of China said that public health was a comprehensive issue and intellectual property rights were but one element of the framework that impacted public health. Given that it was difficult for her delegation to conclude that the Paragraph 6 System in its present form provided an expeditious solution to public health problems, she invited the Council to consider whether there was room for any improvement that could be made to the System. Recommendations could also be made regarding other factors that could have a role in improving public health. Work in the Council would

benefit from looking at any burdensome elements, clarifying the issues and discussing the legal framework as established by the System.

12. Referring to Bill C-393, which had been introduced to the Canadian Parliament and had not been pursued because of elections in May 2011, she wondered whether the domestic debate in Canada had identified burdensome elements in CAMR, which needed to be improved. A review of those elements by the Council could also serve as an example for its work on the functioning of the Paragraph 6 System. She therefore suggested that the delegation of Canada share further information with the Council in that regard. For example, there was a range of conditions established by CAMR which were not required by the Paragraph 6 System, such as the limited list of products to which it applied, the two year limit which applied to any compulsory licence granted under CAMR, as well as limitations on prices and profit margins for genetic manufacturers. Her delegation would like to understand whether those elements had been reviewed in the parliamentary debate in Canada, or whether other WTO Members were concerned about them. For elements also required by the Paragraph 6 System, such as case-by-case decisions on a country-by-country basis or the need to make prior efforts to obtain a voluntary licence first, she asked whether they stood in the way of a well-functioning mechanism that provided effective and expeditious solutions.

13. While some of the elements referred to may have been touched upon, it was possible that they had not been thoroughly explored. As her delegation was not sure whether this could be addressed by the Council and did also not have any experiences to share in this regard, a dedicated workshop with the participation of all stakeholders could be a useful step to answer some of the open questions and to gather experiences. This would allow Members to better understand the functioning of the System.

14. The annual review had already been conducted eight times without reaching a conclusion as to whether the System worked well, provided an effective and expeditious solution, or could be improved. Her delegation was open as to how to conduct the review. If Members agreed that the exchange of experiences had been exhausted at their level, a dedicated open-ended workshop could be conducted in order to better understand the System's functioning and to look at possible recommendations to improve it.

15. The representative of India thanked the delegation of Canada for its role in initiating the implementation of the Paragraph 6 System and supplying much-needed medicines to Rwanda under CAMR. However, the fact that their actual delivery had taken almost three years was a matter of concern, as was the lack of any information on whether patients had received the medicines in time. His delegation had not obtained convincing replies to a number of basic questions during the System's annual reviews which the Council had conducted for several years. It would be interesting to learn more about the debate on Bill C-393 that had taken place in the Canadian parliament, in particular the objections that had been raised. He wondered whether the Bill would be reintroduced and whether the amendments that had been suggested would be reflected in the new version.

16. In response to the questions raised by the delegations of China and India, the representative of Canada said that Bill C-393 had not been put forward or supported by her Government. Since a private member had introduced the Bill, it was not possible to predict whether there would be another initiative of this kind. Her Government had no intention of amending CAMR. It had opposed the Bill because it was convinced that CAMR worked in its present form, reflecting Canada's commitment to improving access to medicines.

17. Taking up the point made by the delegation of India with respect to the time it had taken for the medicines to reach Rwanda, she said that government action had been expedited and the licence had been granted within 15 days. This indicated that the system had worked and that the delay had not been caused by lengthy administrative procedures.

3. Process of acceptance

18. The representative of New Zealand said that her Government had deposited its instrument of acceptance with the WTO on 21 October 2011. In 2008, when the Government had initially agreed to the acceptance of the Protocol, it had been made contingent upon the passage of domestic implementing legislation. Provisions that would enable New Zealand to become an exporting Member under the System had been inserted into the draft Patent Bill, which currently awaited its second reading before Parliament. Having reached the understanding that the acceptance of all WTO Members' entitlement to use the Paragraph 6 System was distinct from the domestic implementation of the System, her Government had agreed to accept the Protocol in advance of the current deadline for acceptance of 31 December 2011. Her delegation remained fully committed to the principles underpinning the Protocol. By accepting the Protocol, it had committed to accepting that the additional flexibilities for all WTO Members became an integral part of the TRIPS Agreement. She encouraged other Members to deposit their instruments of acceptance in order to reach the two-thirds majority required to bring the amendment into force.

19. The representative of Turkey said that her delegation attached great importance to the Paragraph 6 System, which provided additional flexibilities to facilitate access to medicines under the TRIPS Agreement. It supported the entry into force of the Protocol Amending the TRIPS Agreement in order to make the System established under the 2003 Decision a permanent part of the TRIPS Agreement. Her delegation had initiated domestic procedures for the acceptance of the Protocol and hoped to finish them as soon as possible.

20. The representative of Costa Rica said that his country's legislative assembly had approved the acceptance of the Protocol Amending the TRIPS Agreement on 2 October 2011. The instrument of acceptance would be submitted once the remaining formalities were completed.

21. The representative of Indonesia said his delegation had submitted its instrument of acceptance of the Protocol Amending the TRIPS Agreement to the Director-General of the WTO on 20 October 2011. With the WTO Ministerial Conference approaching, he invited Members to seize the momentum and submit their acceptances.

22. The representative of the Secretariat updated the Council on the work of the Secretariat in supporting Members in the acceptance process. In view of the interest that had been expressed during the System's annual review in the Council's meeting in October 2010, the Secretariat had provided further information in order to help Members draw up their instruments of acceptance of the Protocol, based on the discussions that had been recorded in the minutes of that meeting. He stated that many delegations had sought practical information on procedures for the acceptance of the Protocol and that similar questions had often arisen in capacity building activities on TRIPS and public health. The Secretariat had therefore developed a webpage which described the acceptance procedure and provided a model instrument of acceptance.[2]

23. He recalled that a Member could accept the Protocol independent of domestic implementation of the Paragraph 6 System as the two actions were clearly distinct. Acceptance of the Protocol was a legal act whereby a Member expressed its consent that all Members were entitled to use the System. The process of acceptance needed to follow both the relevant Member's own constitutional requirements, and the content requirements which applied to the instrument of acceptance. A Member that wished to take advantage itself of the additional flexibilities provided in the Protocol might need to put in place implementing laws or regulations through normal domestic legislative and regulatory processes. On the other hand, the additional flexibilities under the Paragraph 6 System were already available under the waivers that had been provided in the 2003 Decision. A Member

[2] Available at: http://www.wto.org/english/tratop_e/trips_e/accept_e.htm.

could therefore also choose to put in place domestic implementing legislation before having deposited its instrument of acceptance.

24. The representative of Venezuela said that accepting the Protocol was different from the implementation of the System into domestic legislation, which made the introduction of new flexibilities possible. The fact that his delegation had not yet accepted the Protocol reflected a lack of trust in the System, which would persist until further clarification was obtained. The advent of the TRIPS Agreement had further complicated access to medicines because of the requirement to provide for full patent protection in the pharmaceutical sector. He said that the Members who had signed the Protocol were the main producers of medicines. While the System had been established to address public health problems in an expeditious manner, there was still a need for further clarification of issues related to its functioning and the problems Members were encountering in the process of accepting the Protocol. In support of the delegation of China, he therefore agreed on the importance of having an open-ended workshop, which would involve all key stakeholders, including from civil society and industry. No convincing argument against holding such a workshop had been brought forward since last year's annual review.

4. Capacity building on the Paragraph 6 System and related TRIPS flexibilities

25. The representative of the Secretariat provided an update on technical assistance activities that had been undertaken with a bearing on the Paragraph 6 System and other flexibilities as they related to public health. The implementation, legal and policy context, and the acceptance process of the Paragraph 6 System had been a major theme of technical assistance activities conducted by the Secretariat in increasingly close collaboration with sister organizations, in particular the WHO and WIPO.

26. A specific example of this co-operation was the most recent workshop on intellectual property and public health held by the Secretariat in collaboration with WHO and WIPO. The seventh in its series, the workshop had been a specialist programme for 23 developing country officials that had been convened earlier in the month. Its focus had been building the participants' capacity to help their countries make use of flexibilities for pharmaceuticals under the TRIPS Agreement. To this end, the workshop had utilized presentations, discussions and practical exercises to study the TRIPS Agreement and the management of intellectual property rights as applied to concrete health-related projects. Participants had been familiarized with the key concepts under the TRIPS Agreement and other intellectual property instruments, and how those provisions, including the Paragraph 6 System, could be implemented in national law.

27. Among other issues covered had been pricing and procurement policies as a key element in securing access to medicines, as well as ensuring the safety, efficacy and quality of medicines, technology transfer and local production, the role of competition policy, and intellectual property rights provisions in regional or bilateral free trade agreements and their link to public health.

28. A diverse range of speakers had shared their practical experiences and views on key issues directly relevant to public health, including a wide range of expertise on legal, policy and economic issues from WTO, WHO and WIPO, as well as UNCTAD, representatives from some WTO Members, including Geneva delegations, the Commissioner of the South African Competition Commission, the President of the Ecuadorian Institute of Intellectual Property, the research based and generic industries, Médecins sans Frontières (Doctors without Borders), the Global Fund, the Medicines for Malaria Venture, and Health Action International. These experts had provided a well-rounded view of the issues at the crossroad between intellectual property rights and public health.

29. He said that TRIPS flexibilities in the area of public health had also figured prominently in other WTO national and regional technical cooperation events. In addition, in order to advance co-operation between the WTO, WHO and WIPO and to focus on technical cooperation and enhance available information materials, a series of policy symposia were being undertaken. A third in the series was expected early next year. The working materials developed in this programme of trilateral cooperation, along the lines of the themes and content of the first trilateral symposium held in 2010, were being developed and collated in the form of a trilateral study prepared as a resource for continuing technical cooperation and capacity building. In addition, as a further tool for technical assistance, a set of models for notifications under the Paragraph 6 System had been made available on the WTO website.[3]

30. The representative of WIPO Secretariat recalled that the Development Agenda, agreed upon by the Member States of WIPO in 2007, contained 45 recommendations to enhance the development dimension of the Organization's activities. Key among those were Recommendations 13, 14, 17, 22 and 25, focused on enhancing the understanding and use of flexibilities in the intellectual property system. Since its inception, the Committee on Development and Intellectual Property (CDIP) had met twice each year at WIPO to discuss the planning, implementation and mainstreaming of Development Agenda projects within WIPO's work.

31. As regards the implementation of flexibilities under the Development Agenda, he said that at the fourth session of the CDIP which had been held in November 2009 the Committee had, in the context of discussions on Recommendation 14, requested WIPO to prepare a document on flexibilities in the area of patents. Accordingly, WIPO had prepared a document on Patent-Related Flexibilities in the Multilateral Framework and their Legislative Implementation at the National and Regional Levels (CDIP/5/4 Rev.). At the Committee's request, WIPO had subsequently prepared the second part of the document on flexibilities in patents (CDIP/7/3). In total, those two documents provided information on implementation of ten patent-related flexibilities.

32. At its fifth session, in April 2010, the Committee had requested WIPO to prepare a proposed future work programme on flexibilities for its consideration. At its sixth and seventh sessions, in November 2010 and May 2011 respectively, the CDIP had considered a document setting out a future work programme on flexibilities at WIPO (CDIP/6/10). In response to a request made at the seventh session, the Secretariat had updated the strategy for implementation of the work programme on flexibilities and revised the annex providing details of WIPO's activities in this area, addressing work in the area of patents, and taking stock of WIPO's activities relating to flexibilities in the IP system and technical assistance in the use of flexibilities (CDIP/8/5).

33. He informed the Council of WIPO's implementation of the agreed components of the work programme on flexibilities. Information on IP flexibilities had been incorporated in the WIPO technical assistance programme. The Regional Bureaus and the concerned sectors had been requested to ensure that, at the request of member States, information on flexibilities was appropriately included in the provision of technical assistance.

34. Furthermore, a webpage dedicated to flexibilities in the IP system had been developed and published in English, French and Spanish on the WIPO website.[4] As agreed upon by the member States, the webpage contained (i) a roadmap providing guidance on WIPO's work on flexibilities in the substantive sectors and Committees; (ii) a database containing provisions on national legislation related to flexibilities in the IP system, drawn from the agreed documents on patent-related flexibilities in the IP system; and (iii) links to literature and resources on flexibilities produced by the Secretariat and WIPO-commissioned experts, as well as links to resources on flexibilities produced by

[3] Available at: http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.pdf.
[4] Available at: http://www.wipo.int/ip-development/en/agenda/flexibilities/.

other relevant international organizations, such as the WTO, the WHO, the FAO, and UNCTAD. In this respect, WIPO was actively collaborating with other international organizations involved in work related to flexibilities in order to gather information and ensure a coordinated and effective provision of resources on the issue to the Member States. WIPO had researched and provided links to the work of such organizations, and would continue this outreach to ensure the most effective use of resources in this area.

35. In addition, steps had been taken through internal communications and briefings to ensure that staff involved in providing technical assistance across the sectors of the Secretariat were aware of this strategy on the use of flexibilities in intellectual property, and continued to integrate appropriate techniques for diffusion of information to Member States. Finally, at the request of member States, national and regional level seminars had been organized and were planned in future activities with a view to exchange practical experiences on the implementation of flexibilities. In this respect, in March 2011, a Regional Seminar on the Effective Use of Several Patent-Related Flexibilities had been held in Bangkok, Thailand, involving participants from 16 countries in the Asia and Pacific Region for discussions on patent-related flexibilities and enabling sharing of experiences on the implementation of flexibilities at the national level.

36. The representative of WIPO said that over time, the joint participation of WHO, WIPO and WTO in a number of activities and their participation as observers in respective meetings of the three organizations had contributed to building up a well-functioning working relationship among the three organizations on issues related to public health, intellectual property and trade. This working relationship, which was supported by WIPO's Development Agenda Recommendation 40 to intensify cooperation on IP-related issues with UN agencies, had matured into the informal and practical trilateral cooperation his organization had reported in earlier meetings. One example of this cooperation in the current year was the Workshop on Patent Searches and Freedom to Operate, held on 17 February 2011, which had introduced participants to the basic concepts involved in carrying out patent searches and freedom to operate analyses.[5] Other collaborative activities included (i) the Joint Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate, held on February 18, 2011,[6] which had addressed the growing importance of patent information for public health with respect to freedom to operate strategies, procurement of medicines, technology transfer and setting of research priorities and strategies; (ii) the WTO Workshop on Intellectual Property and Public Health, organized in Geneva by the WTO Secretariat in collaboration with the Secretariats of WHO and WIPO from 10 to 13 October 2011; and (iii) work on a trilateral study on "Promoting Access and Medical Innovation: Intersections Between Public Health, Intellectual Property and Trade" that would be combining the three Secretariats' specific expertise in order to support and objectively inform technical cooperation and policy discussions.

37. He said that the agenda of the 16th session of the WIPO Standing Committee on the Law of Patents (SCP)[7] from 16 to 20 May 2011 had included an agenda item on Patents and Health. The delegation of South Africa had submitted a proposal to the SCP on behalf of the African Group and the Development Agenda Group (SCP/16/7). The WIPO Secretariat, as well as representatives from the WHO and the WTO, had briefed the SCP on work being carried out in relation to that agenda item. The topic would remain on the agenda of the 17th session of the SCP.

38. He also informed the Council that, as of 13 October 2011, the Access to Research for Development and Innovation (ARDI) programme of WIPO had become a full member of Research4Life. Research4Life was a public-private partnership between WIPO, WHO, FAO, UNEP, the International Association of Scientific, Technical and Medical Publishers (STM), Cornell

[5] http://www.wipo.int/meetings/en/details.jsp?meeting_id=22342
[6] http://www.wipo.int//meetings/en/2011/who_wipo_wto_ip_med_ge_11/
[7] http://www.wipo.int/meetings/en/topic.jsp?group_id=61

University, Yale University, and several technical partners, including Microsoft. The goal of the partnership was to enable free or low-cost online access in developing and least developed countries to critical scientific research, with ARDI providing a particular focus on applied science and technology.

39. He drew the Council's attention to the launch of "WIPO Re:Search – Sharing Innovation in the Fight Against Neglected Tropical Diseases"[8] on 26 October 2011. Through WIPO Re:Search, a range of public and private sector institutions had come together to increase the availability of valuable intellectual property assets to the global research community in order to address the challenges represented by neglected tropical diseases, particularly the need for more research. The WHO was supporting this initiative by providing technical advice to WIPO. WIPO Re:Search was founded on the belief that intellectual property and knowledge could be used creatively to stimulate greater investment in research and development for new health solutions. The mechanism worked entirely on a voluntary basis for all participating parties, namely providers and users, and had no impact on any legal instrument. WIPO Re:Search allowed public and private sector organizations to make valuable intellectual property, including compounds, compound libraries, unpublished scientific results, regulatory data and dossiers, screening technologies, platform technologies, know-how licenses and patent licences, available to qualified researchers anywhere in the world seeking to develop new solutions for neglected tropical diseases, malaria and tuberculosis. Licenses for product distribution in least developed countries would be royalty-free.

40. The representative of the WHO Secretariat said that special emphasis had been given in his organization's capacity building activities to the implementation and use of flexibilities in accordance with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. The aim had been to ensure that public health interests were adequately taken into account in the formulation of national policies and legislation on trade and intellectual property. Many of the activities, especially in the field of training, capacity building and technical assistance, thus encompassed TRIPS flexibilities. Support was directed towards assisting Member States on how to safeguard public health interests while adhering to their obligations under international trade agreements. In particular, this included developing public health sensitive patent legislation and incorporating TRIPS flexibilities into domestic legislation. Technical support was carried out in close collaboration with WHO country and regional offices and relevant international organizations.

41. Turning to specific activities, he reported that in March 2011, WHO, along with the United Nations Development Programme (UNDP) and UNAIDS, had published a policy brief on the use of TRIPS flexibilities to improve access to HIV/AIDS treatment. The paper reviewed how countries could use and had used TRIPS flexibilities in order to increase access to HIV treatment. To provide ministries of health in the Eastern Mediterranean Region with a clear analysis of the public health implications of provisions included in bilateral free trade agreements, the WHO Regional Office for the Eastern Mediterranean had also published a policy guide on "Public health related TRIPS-plus provisions in bilateral trade agreements".

42. In 2011, WHO had taught for the first time a module on "Public health and Intellectual Property" in the framework of the Master's Degree in Intellectual Property at the Africa University in Zimbabwe, jointly organized by WIPO, the African Regional Intellectual Property Organization (ARIPO) and Africa University.

43. He recalled that WHO had provided substantial support to the organization of the annual WTO "Workshop on Intellectual Property and Public Health" that took place in Geneva in October 2011. The workshop had addressed TRIPS provisions and flexibilities of relevance to public health as well as other relevant issues ranging from procurement to regulatory questions and prices of

[8] More information available at: http://www.wipo.int/research/en/.

medicines. WHO Headquarters and the WHO European Regional Office had collaborated with WTO in the organization of a Regional Workshop for Central and Eastern European and Central Asian Countries on Intellectual Property and Public Policy that had taken place in Vienna in January 2011. WHO Headquarters and regional offices had also continued providing, upon request and in collaboration with relevant international organizations, technical and policy support to favour use and management of intellectual property in a manner that maximized health-related innovation and promoted access to medical technologies.

44. The representative of the European Union said that it had been reported to his delegation that the WTO Workshop on Intellectual Property and Public Health had provided informative and helpful support to those Members seeking to utilize TRIPS flexibilities. Specific presentations on pricing had been particularly useful. They had clarified that there were many components relevant to the pricing of pharmaceuticals in addition to intellectual property. The inclusion of external speakers with various backgrounds had stimulated an open debate.

45. The representative of Nigeria recognized the work done to build capacity to use the Paragraph 6 System, and asked whether there existed a model voluntary licensing agreement that could be used to guide developing countries in dealing with companies to establish or enhance their local manufacturing capacity.

5. Any alternatives to the use of Paragraph 6 System to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines raised by Members

46. The representative of the United States said that his delegation strongly supported the Paragraph 6 System as established under the 2003 waiver Decision and the 2005 Protocol Amending the TRIPS Agreement in order to allow medicines to be exported under a compulsory license under the terms set out in that decision and the accompanying Chairman's Statement. His delegation had been the first Member to notify its acceptance of the amendment. Members who had already notified their acceptance were developed, developing, and least developed countries and that though some were pharmaceutical producers, most were not. He encouraged other Members to notify their acceptance of the amendment so that the amendment could enter into force.

47. Although the Paragraph 6 System represented an important failsafe, it was only one tool for addressing the larger issue of access to medicines. In discussions with stakeholders in recent years, his delegation had consistently heard that the issue of access to safe and effective medicines was being addressed by a variety of other means. His Government had also been actively working to address the factors that had been shown to reduce access to safe and effective medicines, including tools to deploy trade policy to promote trade in, and reduce obstacles to access, innovative and generic medicines. It had also been supporting the innovation and intellectual property protection that was vital to developing new medicines and achieving other medical breakthroughs.

48. Those tools included (i) enhancing legal certainty for manufacturers of generic medicines; (ii) eliminating tariffs on medicines and medical devices, thereby decreasing costs for hospitals, clinics, aid organizations and consumers, among others; (iii) reducing customs obstacles to medicines by minimizing import barriers, such as discriminatory, burdensome, and unpredictable customs procedures, that impeded access to innovative and generic medicines; (iv) curbing trade in counterfeit medicines by making customs and criminal enforcement measures available to prevent medicines bearing counterfeit trademarks from entering national markets, and thus supporting efforts of countries to address the serious risks to patients posed by such counterfeits; (v) reducing internal barriers to distribution of medicines by guaranteeing importing, exporting, and distribution rights with respect to medicines and minimizing internal barriers that could stand in the way of efficiently distributing medicines to those in need; and (vi) minimizing unnecessary regulatory barriers by

promoting transparent and nondiscriminatory regulatory structures to facilitate the availability of safe and efficacious medicines to the public, while also improving coherence of future rules across the region. He recalled that his delegation had elaborated those systemic issues in the Council's annual review carried out in 2010 (IP/C/M/57, paragraphs 198 to 201). The list of other tools demonstrated that one policy alone could not solve the challenges relating to access to medicines. Rather, a variety of tools, including the Paragraph 6 System, were needed to promote access to medicines.

49. Regarding the proposal of some Members to hold a workshop which would include non-governmental actors, he said that his delegation did not support the idea of having the Council organize such a seminar. Members were free to bring into the Council's review of the Paragraph 6 System perspectives they had gleaned from stakeholders, such as companies or civil society. What Members got out of the review was very much a function of what they put into it. His delegation had hoped that Members would provide information on their experiences as input for the Council's discussions of the System's functioning at the current meeting, but it was disappointed by the details of experiences that had been provided. It could be that the Paragraph 6 System had not been necessary, and for this reason many Members had not implemented it, or that capital-based experts from health ministries could simply not attend the Council's meeting because of other competing demands. He reiterated his delegation's interest in hearing other Members' experiences and views on how best to gather additional information.

50. The representative of Ecuador said that the System was not effective and could be further improved. His Government was therefore not ready to proceed with the acceptance of the Protocol. His delegation, like other Members, had considered alternatives to the use of the Paragraph 6 System by compiling and evaluating other countries' practices in respect of the implementation of Articles 30, 31 and 44 TRIPS. Those practices were of significant importance in enabling Members to take informed policy decisions as they strove to transform into reality the spirit of the Doha Declaration on the primacy and safeguarding of public health and the promotion of access to medicines.

51. In that context, he requested that the European Union provide clarification on the Italian Competition Authority's granting of three compulsory licences between 2005 and 2007, which seemed to have occurred under Article 31(k) of the TRIPS Agreement. Under that provision, the conditions established in Article 31(f) could be waived if a licence was granted to remedy a practice determined after judicial or administrative process to be anti-competitive.

52. In the first case, the Italian Competition Authority had launched an investigation in February 2005 regarding the abuse of dominant position by Merck for its refusal to grant licensing rights in respect of the patent-protected active ingredients, which were used to produce the antibiotic Imipenem Cilastatin. On 21 June 2005, the Italian Competition Authority had granted a compulsory licence on the relevant patents for the active ingredients needed for the manufacture of the antibiotic concerned. The product had been patented only in Italy and not in other European countries. The Italian generics industry had sought a licence to produce and market the product in the rest of Europe (not for the Italian market), where this product had not been protected.

53. The second case concerned a decision by the Italian Competition Authority of 8 February 2006 to grant a compulsory licence for the manufacture in Italy of the patent-protected active ingredient Sumatriptan Succinate needed to produce medicines to treat migraine. The licence had been requested by the chemical company *Fabbrica Italiana Sintetici SpA* (FIS), following GSK's refusal to negotiate a voluntary licence. Initially, FIS had used the compulsory licence primarily for the purpose of supplying the export market by selling its product to generic companies, which marketed it in other countries such as Spain, where the relevant patent had expired. This had been done outside the Paragraph 6 System, from which the EU and its member States had opted out of as beneficiaries.

54. The third case related to the Italian Competition Authority call upon Merck on 21 March 2007 to "grant free licences to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Supplementary Protection Certificate". Finasteride was the active ingredient of a drug initially marketed under the brand names Proscar and Propecia. It was used to treat prostatic hypertrophy, prostate cancer and male pattern baldness. The royalty-free compulsory licences issued by the Italian Competition Authority had remedied Merck's refusal to license its patents to local manufacturers of pharmaceutical active ingredients. Those licences had once again involved exports to other European countries.

55. He asked the delegation of the European Union to provide the Council with further information on these three compulsory licences including, but not limited to, administrative procedures, decision-making processes and the legal and factual basis for the grant of the licences. He also requested that the European Union provide examples of other uses under Article 31(k) relating to the export of medical technologies.

56. The representative of India said that the issue of Members' experiences using alternatives to the Paragraph 6 System to achieve the objective of access to medicines had been raised and discussed for several years, but Members were still short of inputs. He therefore reiterated his delegation's demand for a dedicated workshop that would, as the delegation of Ecuador had mentioned, help strengthen the Paragraph 6 System and where Members would have an opportunity to discuss other experiences. The workshop would also help those delegations develop faith in the System who had cited a lack of faith as the reason for not accepting the Protocol Amending the TRIPS Agreement.

57. Turning to the role of compulsory licensing to provide access to medicines, he recalled that Articles 30 and 31 of the TRIPS Agreement provided a mechanism to that extent. Article 30 was a substantive exception which detailed three criteria to be met for any exception to apply to exclusive patent rights. Article 31, in contrast, was primarily procedural in nature, detailing a list of requirements that applied to other uses without authorization by the patent right holder. Both provisions taken together defined the scope of limitations to exclusive patent rights available under the TRIPS Agreement. Additionally, Article 44 outlined flexibilities with respect to the right to provide permanent injunctions.

58. He drew Members' attention to two particular cases in the United States. Shedding light on those cases could help address the problem of providing access to medicines without recurring to the complicated Paragraph 6 System. In eBay v. MercExchange, the US Supreme Court had determined that the plaintiff in infringement cases had to satisfy a four-factor test before a court could issue a permanent injunction. This four-factor test included demonstration of the following elements by the plaintiff, i.e. that: (i) he had suffered full and irreparable injury; (ii) remedies available at law such as monetary damages were inadequate to compensate for that injury; (iii) considering the balance of hardships between the plaintiff and defendant, a remedy in equity was warranted; and (iv) public interest would not be disserved by a permanent injunction. In Edwards Lifesciences v. CoreValve, a compulsory licence had been granted for manufacturing a medical device in the United States exclusively for exportation. He requested that the United States and other countries where similar judgments had occurred explain to Members why the restrictions on exports under compulsory licences as established by Article 31 of the TRIPS Agreement did not apply in those cases.

59. The representative of Switzerland referred to his delegation's intervention at the last annual review, which was recorded in paragraph 175 of the Council minutes (IP/C/M/64). In response to the question from the delegation of Ecuador on programmes put in place by his Government to address public health problems in developing countries, he noted that his delegation was active in many such programmes. Public health was one of the focus points of its development work at both the bilateral and multilateral levels. As regards programmes specifically linked to intellectual property, he referred to the reports that his delegation had submitted on technical cooperation, as well as on the obligation

under Article 66.2 to provide incentives to transfer technology to least developed country Members. The 2011 report provided more details, in particular in paragraphs 28, 29 and 34 (IP/C/W/558/Add.5). Regarding programmes with a particular focus on development and health, but not specifically linked to intellectual property, more information could be accessed on the website of the Swiss Federal Agency for Development and Cooperation.[9]

60. With respect to any alternatives to the use of the Paragraph 6 System, he referred to his delegation's intervention at last year's annual review (IP/C/M/64, paragraphs 285 to 287). Turning to the proposal for an open-ended workshop to be held to gather information on the functioning of the System, which had been made by some delegations who considered that the exchange of experiences among Members had been exhausted, he maintained his delegation's view that holding such a workshop at this stage was premature. So far, it had not heard much from countries that were potential beneficiaries under the Paragraph 6 System. Most countries that had intervened were either potential exporting countries or countries with manufacturing capacity. However, those were not the countries that WTO Members had had in mind when devising the Paragraph 6 System. While his delegation was not in principle against the idea of holding a workshop, it was important to first establish within the Council the problems that potential beneficiaries had encountered, as well as their concerns with respect to the Paragraph 6 System. Before having heard those concerns, it would be difficult to even decide who should be invited to such a workshop and what specific problems should be highlighted and discussed.

61. The representative of Japan recalled that the Paragraph 6 System aimed at enhancing access to medicines in Members with insufficient or no manufacturing capacities in the pharmaceutical sector. He noted that according to the information that had been provided at the trilateral Symposium on "Access to Medicines: Pricing and Procurement practices" that had been organized by the WHO, WIPO and WTO in July 2010, only 5% of the medicines on the WHO list of essential medicines were protected by patents. Therefore, the Paragraph 6 System was only one of many tools to address public health problems. Other important elements included the procurement of medicines and tariffs.

62. The specific concerns of potential importing Members were indispensable parts of the review. Those Members were best qualified to share their experiences with the Council regarding specific obstacles or concerns faced, but only a few Members had done so. Until discussions within the Council were completed, it would be premature to hold a workshop on the Paragraph 6 System.

63. The representative of Cuba shared the concerns expressed by other delegations on the implementation of the Paragraph 6 System. As regards the acceptance of the Protocol Amending the TRIPS Agreement, she noted that it was the responsibility of Members to create suitable rules that provided a lasting solution and did not require frequent revision. In that context, it was important that further discussions be held in the Council before Members rushed to accept the Protocol. Those should aim at clarifying any doubts about the System's functioning, and address the reasons why it had been rarely used. To this end, the organization of a workshop would be desirable in order to provide greater clarity on the effectiveness of the implementation and operation of the System.

64. The representative of the European Union said that access to essential medicines for developing countries was of utmost importance to his delegation. This explained why it had taken an active part in the negotiations that had led to the 2003 waiver decision and to the TRIPS amendment. Subsequently, it had taken the necessary steps to implement the Paragraph 6 System at the EU level and to accept the amendment. He stressed the need to make the System work, as well as the fact that his delegation was committed to do so. Rather than reopening a debate on the System as a whole, it was important to have a focused discussion within the framework of the Council's annual review. To that extent, the list of issues for discussion which the Chairman had circulated was helpful. However,

[9] http://www.deza.admin.ch/en/home/themes/health

his delegation was disappointed about the debate, as it had hoped to learn more about the reasons why the developing countries for whom the System had been designed, apart from Rwanda, had not used it. He disagreed with those Members that claimed that the operation of the System would be hindered by legal, procedural, commercial and other obstacles. There were few conditions required for the System to work properly.

65. Several reasons could explain why the System had not been used more often. These included the fact that 90 per cent of essential medicines were in the public domain. Least developed countries were also not obliged to implement any TRIPS obligations with respect to patents and test data protection in the area of pharmaceuticals until 1 January 2016. Moreover, there were other channels developing countries could use to get access to cheap medicines, including, for instance, through the use of existing TRIPS flexibilities and direct negotiation with pharmaceutical companies. The Paragraph 6 System was equally effective when it was used as when it was not used due to its effect as both a negotiating chip and a strong deterrent. It would be interesting to hear more about the System's impact on negotiations and on pricing since it had been put in place.

66. In his delegation's view, those who criticized the System as being too burdensome without real life experience of the matter were discouraging developing countries from using an instrument which could help them secure access to affordable medicines. Positions taken by some countries like Ecuador who had said that they would not accept the System were unfair, since those countries had domestic manufacturing capacities that other countries that really needed the System lacked.

67. In response to the questions which the delegation of Ecuador had addressed to his delegation, he said that it was not clear whether those were meant to demonstrate how the System had been put in place or whether they were addressing an unrelated matter, such as the use of compulsory licences under normal circumstances. He clarified that, in any event, European countries were not using the System as importers. Addressing those issues would require some research, but his delegation would be prepared to do so under the relevant agenda item.

68. As regards the two judicial decisions referred to by the delegation of India, the representative of the United States clarified that those decisions had specifically addressed procedural aspects of the provision on injunctive relief. The findings in those cases were therefore limited and the analysis which the delegation of India had made of them was not necessarily within the scope of the matters before the courts.

69. Noting his country's experience regarding the import of generic medicines under the Paragraph 6 System, the representative of Rwanda supported the permanent incorporation of the System through the proposed amendment to the TRIPS Agreement. He informed the Council that his Government would ratify the Protocol Amending the TRIPS Agreement no later than by the extended deadline for acceptance.

70. Taking note of the response given by the delegation of the European Union, the representative of Ecuador further clarified the issues he had raised in his earlier statement. The Paragraph 6 System constituted one of the mechanisms to waive the otherwise applicable condition under Article 31(f) TRIPS and to issue compulsory licences for export purposes. Other provisions that could also assist Members who faced difficulties with the restrictive condition established by Article 31(f) included Article 31(k) which permitted unauthorized usage to remedy a practice determined after a judicial or administrative process to be anti-competitive. In the three cases he had referred to before, compulsory licences had been granted under Article 31(k). His delegation would welcome learning more about such practice, which seemed to represent a valid and useful alternative to overcome problems posed by the implementation of Article 31(f).

6. Next steps and recommendations

71. The Chairman said that the discussion of this topic should provide the Council with an opportunity to discuss whether there was a need for a follow-up to the annual review, and, if so, what it should be.

72. The representative of Venezuela noted that many Members who had intervened on the issue were developed countries who had stated that there was no need to re-open the discussion on the System's functioning. His delegation's concern was that Members who had not yet accepted the Paragraph 6 System and thus could not share their experiences were reluctant to speak on the issue. The fact that they had not implemented the System combined with their silence indicated the existence of unaddressed concerns and the need for greater clarity.

73. The representative of Turkey said that, in the interest of understanding the Paragraph 6 System well, holding a workshop open to all stakeholders could provide a good opportunity to introduce it to potential users. Such a forum would allow the civil society, the pharmaceutical industry, exporting Members and least developed country Members to share their views, experiences, and questions on the implementation of the System.

74. The representative of China said that the Council needed to make a decision regarding the follow-up to the eighth annual review. There appeared to be a lack of consensus among Members on whether the legal procedures or commercial stakeholders prevented developing countries from using the Paragraph 6 System. Her delegation therefore strongly supported that an open-ended workshop for all stakeholders be held. It would help achieve greater transparency, promote a holistic understanding, and perhaps a solution to the current deadlock.

75. The representative of Canada supported the delegations of Switzerland and Japan in that it would be useful to hear more specific views and experiences from potential beneficiaries regarding any obstacles posed by the System. It was not clear what could be gained from an open-ended workshop that could not be gained through discussions in the Council. Delegations could gather information from stakeholders and share it with the Council.

76. The representative of the European Union said that his delegation shared the views expressed by the delegations of Canada, the US, Japan, and Switzerland. Experiences with the System heard so far either indicated that the System had worked, that it had had some impact even when it had not been used in the end, or that it had been a useful negotiating chip. Holding an open-ended workshop would therefore be premature and unnecessary.

77. The Chairman suggested that he consult on next steps, including the issue of a possible workshop.

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

79. Turning to the draft report to the General Council on the annual review of the Paragraph 6 System, the Chairman recalled that the Secretariat had circulated a draft cover note for the Council's report modelled on previous years' reports (JOB/IP/4). It contained factual information on the implementation and use of the System established under the Decision, discussions regarding its operation, and the status of acceptances of the Protocol Amending the TRIPS Agreement. In accordance with the way that the Council had prepared its reports in the previous years, the portion of the minutes of the meeting that reflected the discussions held under the specific agenda item could be attached to the cover note.

80. As regards paragraph 15 of the report, he recalled that Argentina, Indonesia and New Zealand had recently accepted the Protocol. There was also a minor error in the paragraph, namely that Uganda should have been included in the list of Members that had notified their acceptance. This paragraph would be updated and corrected accordingly.

81. The Protocol had originally been open for acceptance by Members until 1 December 2007. Upon proposals by the TRIPS Council, the General Council had twice extended that period for further two-year periods. The period for acceptance was currently due to expire on 31 December 2011. Given the proximity of that date, the Chairman suggested that the Council consider again submitting a proposal to the General Council for a decision to extend the period for the acceptance of the Protocol. For that purpose, a draft decision that could be submitted to the General Council for adoption was included in Annex 2 to the draft report. It did not yet contain a new deadline for the extended period for acceptances. In the light of the consultations he had held on this matter, he suggested that the Council propose to extend the period by a further two years until 31 December 2013.

82. The representative of Turkey supported the approach suggested by the Chairman. This would also provide her delegation with additional time to complete its internal procedures.

83. The Chairman proposed that the Council agree on forwarding to the General Council the proposal for a decision to extend the period of acceptance by Members of the Protocol Amending the TRIPS Agreement until 31 December 2013. He suggested that the last paragraph of the draft decision by the General Council contained in Annex 2 to the draft report (JOB/IP/4) be complemented by inserting this date. He also proposed that the Council agree to the cover note to the report contained in JOB/IP/4, and also that the Council minutes containing the record of the discussion be attached to it.

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

ANNEX 2

WORLD TRADE ORGANIZATION

WT/L/…

(11-0000)

AMENDMENT OF THE TRIPS AGREEMENT – THIRD EXTENSION OF THE PERIOD FOR THE ACCEPTANCE BY MEMBERS OF THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Draft Decision of [date]

The General Council,

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the Marrakesh Agreement establishing the World Trade Organization (the "WTO Agreement");

Having regard to paragraph 2 of the Decision of the General Council of 6 December 2005 on the Amendment of the TRIPS Agreement (the "TRIPS Amendment Decision") and paragraph 3 of the Protocol Amending the TRIPS Agreement (the "Protocol")[1], which provide that the Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference;

Recalling that the General Council, by its decision of 17 December 2009 (the "2009 Extension Decision")[2], extended the period for acceptances of the Protocol by Members for the second time until 31 December 2011 or such later date as may be decided by the Ministerial Conference;

Recalling also that, pursuant to paragraph 3 of the TRIPS Amendment Decision and paragraph 4 of the Protocol, the Protocol shall take effect and enter into force in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement;

Noting that acceptance of the Protocol by two thirds of the Members in accordance with paragraph 3 of Article X of the WTO Agreement is taking longer than initially foreseen;

Having considered the proposal to further extend the period for acceptances of the Protocol submitted by the Council for TRIPS (IP/C/..);

Decides as follows:

The period for acceptances by Members of the Protocol Amending the TRIPS Agreement referred to in paragraph 2 of the TRIPS Amendment Decision and paragraph 3 of the Protocol,

[1] WT/L/641.
[2] WT/L/785.

and extended by the 2009 Extension Decision, shall be further extended until 31 December 2013 or such later date as may be decided by the Ministerial Conference.