



WORLD TRADE ORGANIZATION
ORGANISATION MONDIALE DU COMMERCE
ORGANIZACIÓN MUNDIAL DEL COMERCIO

Direct line: (+41 22) 739 53 72
Direct fax: (+41 22) 739 57 77

OHCHR REGISTRY

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Recipients : ..M.M...Darrow
 ..J...Heenan

Mr. Mac Darrow
Coordinator a.i.
MDGs and Right to Development Unit
Research and Right to Development Branch
United Nations High Commissioner for Human Rights
Palais des Nations
1211 Genève 10

Div. Reference:
Reg. Reference: **ORG/605 06-4865**

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Dear Mr. Darrow,

We have received your request dated 13 October 2006, on Resolution E/CN.4/RES/2005/84 "The protection of human rights in the context of human immunodeficiency virus (HIV) and required immunodeficiency syndrome (AIDS)". I would like to inform you that the WTO does not have any specific activity or programme to deal with HIV-related human rights of women, children and vulnerable groups in the context of prevention, care and access to treatment.

However, should you require a background on the WTO provisions related to access to essential medicines, and the Protocol amending the TRIPS Agreement, you may wish to note that in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Ministers recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Following their instructions to find an expeditious solution to this problem, the General Council on 30 August 2003 adopted the Decision on the "Implementation of Para 6 of the Doha Declaration on the TRIPS Agreement and Public Health", which contains three waivers with respect to pharmaceutical products. Pursuant to paragraph 11 of this Decision, the Council for TRIPS prepared an amendment of the TRIPS Agreement replacing the waiver provisions. The General Council on 6 December 2005 adopted the Protocol amending the TRIPS Agreement and submitted it to WTO Members for acceptance by 1 December 2007. The Protocol will enter into force upon acceptance by two thirds of the Members. In the meantime, the waiver provisions of the August 2003 Decision remain in force.

For more details on the implementation and use of the paragraph 6 system and the Decision on the Amendment to the TRIPS Agreement, you can read the attached document (IP/C/42 of 2 November 2006).

Yours sincerely,

Willy Alfaro
Director
External Relations Division

**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 second annual review took place in October 2005 and the General Council took note of the Council for TRIPS' report (IP/C/37) at its meeting on 1-2 December 2005 (WT/GC/M/100, para. 95). This report covers the period since October 2005.
3. At its meeting of 25-26 October 2006, the Council took up the annual review. The annex to this report records the statements made in the review. The paragraphs below set out factual information regarding the implementation of the 2003 Decision, the work pursuant to its paragraph 11 on the amendment to the TRIPS Agreement and the Decision on an Amendment to the TRIPS Agreement.

Information on implementation and use of the system established under the Decision

4. As foreseen in the 2003 Decision, the Secretariat has established 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/public_health_e.htm). To date, there have been no notifications made to the Council for TRIPS of the use of the system pursuant to paragraphs 1(b), 2(a) and 2(c) of the Decision.
5. The delegation of the European Communities informed the TRIPS Council at its meeting of 14-15 June 2006 that it had adopted Regulation 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. The Regulation had been published in the Official Journal of the European Union on 9 June 2006 and would enter into force on 29 June 2006. It said that this created the legal basis for the granting of compulsory licenses for export purposes, in line with the WTO General Council Decisions of 30 August 2003 and 6 December 2005. Further details of the European Communities' implementing legislation can be found in the minutes of that meeting (IP/C/M/51, paras. 5-6) and in the European Communities' notification pursuant to Article 63.2 of the TRIPS Agreement (IP/N/1/EEC/P/5).

Decision on the Amendment to the TRIPS Agreement

6. Pursuant to paragraph 11 of the 2003 Decision, in autumn 2005 the Council continued its work on the amendment to the TRIPS Agreement to replace the provisions of the waiver Decision. At the meeting of the Council for TRIPS on 6 December 2005, the Council agreed to submit, in accordance with Article X:1 of the WTO Agreement, a proposal for a decision on an amendment to the TRIPS Agreement (IP/C/41) to the General Council, attached to which was a proposal for a Protocol Amending the TRIPS Agreement. Along with the draft decision, the Council also approved the forwarding of the text of a "Chairman's statement" (JOB(05)/319 and Corr.1), as well as the text of a "Chairman's statement concerning paragraph 4 of Article 31*bis* of the proposed amendment to the TRIPS Agreement" (JOB(05)/320), both to be made by the Chair of the General Council prior to the adoption by the General Council of the proposal.

7. At the meeting of the General Council on 6 December, the Chair of the Council for TRIPS informed Members of the recommendation of the Council for TRIPS for action by the General Council. The Chair of the General Council made the statement forwarded by the Council for TRIPS in document JOB(05)/320 and then read out the Chairman's statement forwarded by the Council for TRIPS in document JOB (05)/319 and Corr.1. The Chair then proposed that the General Council take note of the statements and, in the light of the Chairman's statement, adopt the draft Decision in document IP/C/41 (subsequently circulated in document WT/L/641). The General Council so agreed. It also agreed that the statements made after the adoption of the 2003 Decision were to be considered as reaffirmed by the Members concerned.

8. Pursuant to paragraphs 1 and 2 of the General Council's Decision of 6 December 2005 (WT/L/641), the Protocol Amending the TRIPS Agreement attached to it has been submitted to Members and is open for acceptance until 1 December 2007 or such later date as may be decided by the Ministerial Conference. 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.

9. The following Members have notified the acceptance of the Protocol Amending the TRIPS Agreement:

- United States, 17 December 2005, WT/Let/506,
- Switzerland, 13 September 2006, WT/Let/547, and
- El Salvador, 19 September 2006, WT/Let/548.

ANNEX

**EXCERPT FROM THE MINUTES OF THE COUNCIL'S MEETING OF
25-26 OCTOBER 2006 TO BE CIRCULATED AS IP/C/M/52¹**

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

1. The Chairman recalled that paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health provided that the Council for TRIPS should review annually the functioning of the system set out in the Decision with a view to ensuring its effective operation and should annually report on its operation to the General Council. Furthermore, the paragraph provided that this review should be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

2. He said that the Secretariat had prepared a draft cover note to the Council's report modelled on that of last year's report, which had been circulated as JOB(06)/244. The draft cover page contained factual information on the implementation and use of the system established under the Decision and on the work on the preparation of an amendment to the TRIPS Agreement pursuant to paragraph 11 of the Decision. He proposed that the part of the minutes of the meeting reflecting the discussions held under this agenda item be attached to the cover note. This format would follow the way that the Council prepared its report last year.

3. As regards the status of acceptances of the Protocol Amending the TRIPS Agreement that was done at Geneva on 6 December 2005, he said that Switzerland and El Salvador had notified, respectively, their acceptance of the Protocol on 13 and 19 September 2006 (documents WT/Let/547 and 548). He also recalled that the United States had notified its acceptance on 17 December 2005. Therefore, to date, three Members had accepted the Protocol, which would enter into force for these Members upon acceptance of the Protocol by two thirds of the Members.

4. The Chairman recalled that the Protocol was open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference. As this date was only a little over a year away, he encouraged Members to ensure that necessary measures were being taken in capitals to allow the consideration of the acceptance in a timely fashion. With a view to regularly updating the Council on the state of play in regard to acceptances, he suggested that the Secretariat be requested to prepare a note setting out the status of acceptances, which would be updated for each meeting of the Council.

5. The representative of El Salvador considered that the Protocol represented a triumph in the WTO negotiations on public health, which was unprecedented and highly beneficial for developing countries and least-developed countries. The Decision adopted in December 2005 would establish additional flexibilities under the TRIPS Agreement as it related to public health. Countries with no or insufficient domestic manufacturing capacities would have the right to import patented medicines produced abroad by making use of compulsory licences under the paragraph 6 system. This already formed an integral part of her country's intellectual property legislation. The system would make it possible for a country with manufacturing and export capacities to authorize the use of a compulsory licence to permit the production of medicines for export to countries in need of such medicines which have no or insufficient supply capacity.

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.

6. The representative of Canada updated Members on the Canadian Access to Medicine Regime, which had come into effect on 14 May 2005. Her delegation was committed to ensuring that the regime was effective, responsive, transparent and accessible to countries that had an interest in using it in their efforts to combat HIV/AIDS, tuberculosis, malaria and other epidemics. In August 2006, Canada's Minister of Health had announced an immediate and comprehensive review of the Access to Medicine Regime in consultation with stakeholders. The review had been built into the legislation because Canada was one of the first WTO Members to implement the August 2003 Decision and had had to address many key legal and policy issues for the first time. The review would provide an opportunity to identify ways in which a regime could better meet its humanitarian objectives without derogating from international trade obligations and to compare the Canadian legislation with that of other WTO Members which had now implemented the Decision.

7. She recalled that, under the Access to Medicine Regime, Canada had started with an initial list of drugs recognized by the WHO as being essential to the health needs of citizens around the world. The list would minimize the discretion of Canada's Commissioner of Patents in deciding whether to issue a compulsory licence and could be amended to reflect the evolving public health needs of developing and least-developed countries. It had already been amended twice. The first amendment was in response to a request from a non-governmental organization and a Canadian drug manufacturer to add a fixed-dose combination HIV/AIDS therapy. It had passed Health Canada's regulatory review and was now listed on the WHO's prequalification list. Also at the request of a local manufacturer and a non-governmental organization, the second amendment had added *Oseteltamivir*, an antiretroviral drug for the prevention and treatment of the influenza virus. The system was in place and the fixed-dose combination HIV/AIDS therapy was available. All that would remain was for an eligible importing country to request it.

8. To provide information on the regime, her government had developed a CD-Rom that explained the system, the procedures and the documentation. The same information was also available at a special website created for the Access to Medicines Regime (www.camr.gc.ca). Canada's experts stood to provide further information. If potential users did not find the regime to be a feasible option, or did not consider it to be the right choice, her delegation would welcome their feedback. Her delegation would keep Members informed of the results of the domestic review, which was due to be completed by May 2007.

9. The representative of Benin, speaking on behalf of the African Group, said that the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health was of vital importance for the African Group, and particularly for the least developed countries belonging to that group. The process under way for the amendment of the Agreement would enable countries having insufficient or no capacities for the production of medicines to benefit from flexibilities in the form of licences to be granted by WTO Members possessing infrastructure for the production of medicines for export to countries lacking such capacities. African countries would work with their trading partners to implement the Decision.

10. The representative of Switzerland agreed with the Chairman that Members should be encouraged to proceed swiftly to the acceptance of the Protocol Amending the TRIPS Agreement.

11. The representative of Kenya said that his delegation was in the process of depositing its instrument of acceptance of the Protocol. His delegation was seeking assistance from the Commonwealth Secretariat to implement the Decision.

12. The representative of the European Communities informed the Council that his delegation was in the process of accepting the Protocol.

13. The Council agreed on the draft cover note to the report and that the record of the discussion be attached to it, and that the Secretariat be requested to prepare a note on the status of acceptances of the Protocol Amending the TRIPS Agreement, which would be updated for each meeting of the Council.
