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Council for Trade-Related Aspects of Intellectual Property Rights

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THE TRIPS AGREEMENT AND PUBLIC HEALTH

Communication from Canada

The following communication, dated 24 October 2005, is being circulated at the request of the Delegation of Canada. It was circulated as an advance copy for the Council's October 2005 meeting.

Further to the last TRIPS Council meeting of 14-15 June 2005, Canada is pleased to present a description of the functioning of Canada's system with respect to the implementation of the 30 August Decision on TRIPS and Public Health.

Delegations seeking additional information or clarification are invited to contact the Permanent Mission of Canada directly.

I. CANADA'S IMPLEMENTATION OF THE 30TH AUGUST DECISION ON TRIPS AND PUBLIC HEALTH

1. Canada has implemented the WTO's 30th August Decision on TRIPS and Public Health (the "Decision") through amendments to both its *Patent Act* and its *Food and Drugs Act* and to a series of subordinate regulations. These amendments, which came into force on 14 May 2005, establish the procedure to be followed by domestic pharmaceutical manufacturers who wish to apply for a compulsory licence to manufacture a generic version of an eligible patented pharmaceutical product for export to an eligible importing country. The following is a summary of Canada's regime.

A. ELIGIBLE IMPORTERS

2. Although the Decision is an agreement between WTO Member countries, for humanitarian reasons, Canada has opted to implement it in a manner that enables both WTO and non-WTO Member countries to import pharmaceutical products under licence. Schedules 2, 3 and 4 of Canada's *Patent Act* list the countries eligible to make use of the regime. While non-WTO least-developed countries are automatically eligible to import under the Canadian regime, non-WTO developing countries may only do so upon request and on the condition that they be eligible for official development assistance according to the Organisation for Economic Co-operation and Development (OECD).

3. In order for an eligible importing country to avail itself of the Canadian regime, it must publicly disclose the name and quantity of the product it is seeking, and, if that product is protected by a domestic patent, indicate that it has or will be issuing a compulsory licence authorizing imports of the product. Unless the importer is a least-developed country, notice of the above information must also contain a declaration that it has no or insufficient capacity to manufacture the required product.

More highly developed countries, which are listed on Schedule 4, must also indicate that they require the patented product to respond to a public health emergency. WTO Member countries must provide notice of the above information to the WTO, copies of which will be posted on a website which has been established for that purpose. All other countries must provide notice to the Government of Canada, through diplomatic channels, copies of which will be posted on a website maintained by Canada's Minister of Foreign Affairs.

4. Non-governmental organizations may act as purchasers of licensed pharmaceutical product under Canada's regime, with the permission of the importing country's government.

B. ELIGIBLE PHARMACEUTICAL PRODUCTS

5. Products eligible for export under Canada's regime are listed in Schedule 1 of the *Patent Act*. Schedule 1 is composed primarily of products on the World Health Organization's (WHO) Essential Medicines List which are patented in Canada. The Schedule will be amended from time to time to ensure that the list of eligible products remains current with the public health needs of developing countries. To facilitate this process, the *Patent Act* provides for the creation of an expert committee to advise the Canadian Government on the need to add products to the list. Schedule 1 was recently amended for the first time by the addition of a fixed dose combination anti-retroviral medication used in the treatment of HIV/AIDS.

6. Although not required by the Decision, at the request of Canadian pharmaceutical manufacturers, all products to be exported under Canada's regime must meet the same safety, efficacy and quality standards as drugs destined for domestic consumption. A special review stream has been established by Canada's Minister of Health in order to expedite the approval of such products and the applicable fees normally associated with the regulatory review process will be remitted upon meeting certain criteria, once it has been established that a compulsory licence has been issued to the applicant in respect of the approved product.

C. APPLICATION PROCESS

7. A Canadian pharmaceutical manufacturer that has entered into a contract with an eligible importing country for the supply of an eligible pharmaceutical product must file an application for an export licence with Canada's Commissioner of Patents (the "Commissioner"). The application must identify, *inter alia*, the pharmaceutical product for which a licence is sought, the patent(s) which protects it, the quantity to be manufactured, the country to which it is to be exported and the identity of the purchaser. Here too the fees normally associated with a compulsory licence application have been waived.

8. In keeping with Article 31(b) of TRIPS, the application must also include a declaration that the applicant had, at least 30 days prior to applying for the compulsory licence, unsuccessfully sought a voluntary licence from the patentee and, in doing so, provided the latter with information that is substantially the same as the information appearing in the application. This declaration must be accompanied by, in the case of a WTO Member, a copy of that country's notification to the WTO of its intention to import the product to which the application relates and, in the case of a non-WTO Member, a copy of the country's notice to the Government of Canada of its intention to import that product. In either case, the applicant must also provide the Commissioner with a declaration setting out the patent status of the product in the importing country.

9. The manner in which the above information is communicated to the Commissioner is prescribed by Canada's *Use of Patented Products for International Humanitarian Purposes Regulations*. Form 1 of these regulations sets out the information which must appear in the application itself. Form 2 sets out the information which must appear in the applicant's declaration

that it unsuccessfully sought a voluntary licence from the patentee. Forms 3 to 7 set out the information which must appear in the applicant's declaration as to the identity of the pharmaceutical product and its patent status in the importing country (whichever of Forms 3 to 7 applies in the circumstances will depend on whether the importing country is a WTO or non-WTO Member and on the patent status of the product in that country.

10. If the application meets the content requirements described above, specifies an eligible product on Schedule 1 which has been approved by the Minister of Health, and names a country on Schedule 2, 3 or 4, the Commissioner is required to grant the applicant a compulsory licence to manufacture and export the product in question. The actual content of the licence issued by the Commissioner is set out at Form 9 of the above named regulations.

D. THE GOOD FAITH CLAUSE

11. The Decision was adopted by the General Council in light of the General Council Chairperson' s statement stipulating that it must be used in good faith in order to deal with public health problems and not for commercial policy objectives. A provision in Canada's *Patent Act*, which has come to be known as the "good faith clause", gives effect to Canada's obligation to implement the Decision in keeping with the Chairperson's statement by providing patent holders with the right to challenge an export licence in court where there is good cause to believe it is predominantly commercial, as opposed to humanitarian, in nature.

12. In order to bring such a challenge, the patent holder must first establish that the average price of the licensed product is 25% or more of the average price of the equivalent patented product in Canada. If this test is met, the court will look to the other merits of the application and determine, based on a number of statutory considerations, whether the licence is commercial in nature. An absolute defence exists to any such challenge if the licence holder can establish that the product's average price remains less than its direct supply cost plus 15%.

13. If the court determines that the agreement is commercial in nature, it may make an order, on any terms that it considers appropriate, either terminating the licence or requiring the licence holder to pay, in addition to the royalty otherwise required to be paid, an amount that the court considers adequate to compensate the patent holder for the commercial use of its patent.

E. ANTI-DIVERSION MEASURES

14. Also in keeping with the Chairperson's statement, Canada's regime contains a number of measures designed to promote transparency and minimize the risk of diversion. Most notably, the product to be exported must be distinctive from the version sold in Canada (i.e., of a different colour) and the product and/or its label must bear the mark 'XCL' to indicate that it was produced for export under a compulsory licence.

15. In addition, before a pharmaceutical product subject to a licence may be exported, the licence holder must establish a website setting out information about the name of the licenced product, its distinguishing characteristics, the identity of the importing country, the amount to be manufactured and sold for export, as well as information identifying every known party who will be handling the product while it is in transit from Canada to the importing country.

16. Lastly, the licence holder must provide, within 15 days before the product is exported, a notice specifying the quantity to be exported, as well as every known party that will be handling the product while it is in transit. This notice must be provided to the patent holder(s), the country named in the application and the person or entity that has purchased the product.

F. ROYALTIES

17. Paragraph 3 of the Decision calls for "adequate remuneration" to be paid to the patentee on a case-by-case basis, taking into account the economic value to the importing country of the use that has been authorized by the exporting country. Under Canada's regime, the royalty is calculated by multiplying the monetary value of the supply agreement between the licence holder and the importing country by an amount which fluctuates on the basis of that country's standing on the United Nations Human Development Index (UNHDI).[1] The formula to determine the royalty rate is: 1, plus the number of countries on the UNHDI, minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. For example, in 2004 Nigeria was ranked number 151 of the 177 countries listed on the UNHDI . Therefore, the royalty rate that would be applicable to exports of pharmaceutical products to Nigeria would be [(1+177-151)/177] x 0.04 = 0.0061 or 0.61 percent.

G. TERMINATION BY FEDERAL COURT

18. Finally, the court may also make an order terminating an export licence where the patent holder can establish that one of the following events has transpired:

- the application for the licence contained materially inaccurate information;
- the licence holder has failed to establish a website;
- the licence holder has failed to provide an export notice;
- the licence holder has failed to pay the prescribed royalties;
- the licence holder has failed to provide a copy of its supply agreement;
- the product has been re-exported in a manner contrary to the Decision;
- the product has been exported in a quantity greater than the quantity authorized to be manufactured under the licence;
- Where the importing country is a non-WTO Member, that country has failed to adhere to the principles underlying the Decision.

19. A copy of Canada's implementing legislation, An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa) can be obtained electronically at:

- http://www.parl.gc.ca/PDF/37/3/parlbus/chambus/house/bills/government/C-9_4.PDF

and the Regulations at:

- http://canadagazette.gc.ca/partII/2005/20050601/pdf/g2-13911.pdf

[1] Where the importing country is not listed on the UNHDI, the royalty is to be calculated by substituting the individual country's rank in the formula with the average rank of all countries appearing on the same Schedule. However, an exception to this rule has been made in the case of non-WTO Member developing countries that are unranked. Although these countries are individually eligible for listing on Schedule 4, their individual rank in the formula will be replaced by the average rank of all countries appearing on Schedule 3, as the latter is thought to better reflect the level of development of the countries in question.