Fixing Canada's Access to Medicines Regime: Open Letter to WTO Members Regarding review of Doha Paragraph 6 Mechanism on Access to Medicines

Canadian HIV/AIDS Legal Network | Réseau juridique canadien VIH/sida

October 27, 2010

Dear WTO Members:

We note that on October 27th, you are meeting in the Council for TRIPS for a day-long discussion of the WTO General Council Decision of August 30, 2003. As you know well, this Decision was intended to be the "expeditious solution" to the problem identified in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (in 2001) – namely, that countries lacking sufficient manufacturing capacity in the pharmaceutical sector "could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."

We regret that your deliberations are open only to WTO Members and Observers, and that you have not included the opportunity for civil society organizations to participate and share their perspectives. There are such organizations that have extensive, direct experience of the implementation of the Doha Paragraph 6 System and of the difficulties encountered in the efforts made to date to use it. In our view, such perspectives are critical to any honest assessment of the experience to date with the system.

We are a civil society organization actively engaged in the global effort to protect public health and to promote access to medicines for all -- the very objective unanimously affirmed by WTO Members in the Doha Declaration (paragraph 4) -- and in particular with efforts to render the Doha Paragraph 6 System workable in practice in the Canadian context. We therefore wish to share some perspective with you as you embark upon your deliberations.

As you know, Canada was one of the first countries to implement the August 30th, 2003 General Council Decision in its domestic law - and, as you know, **"Canada's Access to Medicines Regime" (CAMR)** is the only implementation of the Decision that has yet been tested and used to secure one compulsory licence. As you also know, there has been only one use of the Canadian legislation, to supply one country (Rwanda) with one fixed-dose combination AIDS drug (15.6 million tablets of Apo-Triavir, consisting of 300 mg zidovudine, 150 mg lamivudine and 200mg nevirapine).

Apotex Inc., the generic manufacturer that has used this system -- in the sole such use of the August 30th, 2003 Decision to date in the world -- has indicated repeatedly, including in testimony before our Parliament, that it does not wish to

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use the mechanism again in its current form. You can read Apotex's account, before our Parliament, of its attempts to use CAMR at http://www.parl.gc.ca/40/2/parlbus/commbus/senate/Com-e/bank-e/11cv-e.htm?Language=E&Parl=40&Ses=2&comm_id=3.

Similarly, one non-governmental organization, Médecins Sans Frontières (MSF), worked intensively for years to attempt to make use of the August 30th, 2003 Decision to procure this particular product under a compulsory licence to be issued under CAMR, but ultimately abandoned that effort. For a more detailed chronology of this experience, and the barriers encountered, see MSF's brief "Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable" at http://www.msf.ca/features/aids2006/files/REP_JCPA_en.pdf.

One significant problem encountered in the effort by Apotex and MSF to make use of the system was the requirement, under the Canadian legislation, that the process of seeking first a voluntary licence and, if unsuccessful, then a compulsory licence, for export was contingent upon naming a specific importing country as a precondition. According to the Government of Canada's own review of the legislative regime in 2007:

> "In testimony before [the House of Commons], representatives of the [generic] company indicated they had been prepared to seek an export licence as early as July of 2006, but were unable to proceed to the application stage of this process because of the requirement that they identify an eligible importing country in the voluntary licence request to the patent holder." [Government of Canada, Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act, 2007]

As a result of this precondition of seeking a compulsory licence, it took more than 2 years to get to the issuance of the first compulsory licence under CAMR. You will almost certainly hear from the Canadian government that "it took only 68 days from start to finish for the compulsory licensing procedure to be completed". This is simply a misleading characterization of the actual history - it is an account of the one experience to date of using the Doha Paragraph 6 system that conveniently omits the significant delay caused by the insistence on making any compulsory licence conditional upon first disclosing to the patent-holder(s) the name of a single, specific country that would seek to import medicines manufactured under a Canadian-issued compulsory licence. We invite you to challenge this misleading account of the actual operation of the system -- and to reflect upon what this should mean for WTO Members in clarifying future aspects of the August 30th, 2003 Decision or indeed revisiting the Decision in its entirety.

In addition to requiring a separate licensing process for each and every country, with a specific country identified in advance of being able to seek a licence, Canada's legislation implementing the August 30th , 2003 Decision contains a

number of other restrictions that further hinder its user-friendliness for either generic manufacturers or eligible importing countries. These include the following:

- The licence is limited to supplying a "maximum quantity" of a medicine, which quantity must be stated in advance as part of the process of seeking a voluntary licence from the patent-holder(s) or a compulsory licence from the Commissioner of Patents. Any subsequent change in the quantity sought to be purchased by the importing country would require initiating the process all over again, including efforts to negotiate a voluntary licence. You will appreciate, as WTO Members, that the August 30th, 2003 Decision only refers to a requirement that countries notify the TRIPS Council of the "expected quantities" of a pharmaceutical product, not a "maximum quantity".

- Any licence issued under Canada's legislation is limited to a maximum term of 2 years. Nowhere in TRIPS or the August 30th, 2003 Decision is any such arbitrary limitation required. Canada is, of course, free to legislate such a limit, but it should be fairly obviously that such a limitation, in addition to the other unnecessary restrictions described here, further contributes to the use of such a system being a less economically viable proposition for a generic manufacturer and a less flexible system for addressing the evolving needs of eligible importing countries. (There is a provision in the Canadian legislation allowing for a "renewal" of an issued compulsory licence for up to an additional 2 years; however, Members should be clear that this is only an extension of the time during which the generic manufacturer can complete exportation of the "maximum quantity" of the product originally authorized by the compulsory licence. It is NOT a mechanism that allows any additional quantity of the product to be exported.)

We do note one aspect of Canada's legislation that is, in our view, a positive feature of its implementation of the August 30th, 2003 Decision -- a feature based on suggestions made by Canadian NGOs during the drafting of the original legislation, and one that we feel warrants careful consideration by other Members implementing the August 30th, 2003 Decision. Specifically, we refer to the clear definition in the Canadian law of the "adequate remuneration" that must be paid, pursuant to TRIPS Article 31(h), by the licensee to the patentee in the event of a compulsory licence issuing. The Canadian regime includes a formula for calculating the royalty payable in any given instance based on the ranking of the importing country on the UN's Human Development Index, with a maximum royalty payable capped at 4% of the value of the contract between a generic manufacturer exporting under compulsory licence and the purchaser in the eligible importing country. Such a feature provides an important degree of clarity and certainty to all parties involved, including the generic manufacturer, as to an important cost of using the system that must be taken into account when considering whether to embark upon its use or in bidding to supply a given country with that generic product.

We invite you to learn more about the Canadian experience than will almost certainly be presented to you by the Government of Canada, which has consistently maintained that there is no need to make any changes to Canada's law -- in the face of ample evidence of the difficulties of using it and the complete absence of any indication that it will be used again in the future, beyond the one test use made of it to date. Indeed, the Government is currently actively resisting proposed legislation in our Parliament that would streamline Canada's legislation implementing the Doha Paragraph 6 system while conforming with Canada's obligations under the TRIPS Agreement and the August 30th, 2003 Decision.

In particular, the Government is resisting proposals that would simplify the current Canadian legislative regime so as to permit:

a) The supply of multiple eligible importing countries under a single compulsory license; and,
b) The licence-holder to respond more easily, under that single licence, to the needs of eligible importing countries for quantities of medicines that may and will change over time.

Such proposals would render Canada's regime more straightforward, more responsive to the needs of eligible importing countries, and more economically viable as a proposition for generic manufacturers who are would-be users of the regime. A range of experts have formed the view that the essential elements of the Bill C-393, the bill with the above reforms to CAMR that is currently being debated by a Parliamentary committee this week in Ottawa, are compliant with Canada's obligations as a WTO Member.

A broad range of Canadian civil society organizations -- AIDS organizations, the Grandmothers to Grandmothers Campaign, humanitarian organizations, student groups and more -- have for many years been advocating for such changes. You will find online an extensive collection of material on this subject, including extensive testimony from civil society groups and experts, Canadian and international, who have identified the need for reforms to Canada's Access to Medicines Regime and whose testimony and submissions before our Parliament in the past 2 weeks have made a powerful case for why a better, more workable system is needed. This material is online at http://www.aidslaw.ca/EN/camr/index.htm#Documents.

We would like to steer your attention in particular to the following three documents that provide more detailed analysis of the flaws in the current Canadian legislation implementing the August 30th, 2003 Decision and the rationale for the proposed reforms that would render the regime a more viable solution:

- “Fixing Canada’s Access to Medicines Regime: 20 Questions & Answers” http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=965.

- "Making CAMR Work: Streamlining Canada's Access to Medicines Regime" (a brief by the Canadian HIV/AIDS Legal Network to the Parliamentary committee studying Bill C-393) http://www.aidslaw.ca/EN/camr/documents/CHLN_BillC-393_INDUbrief_21Oct2010_EN.pdf.

- "Bill C-393: Key features and compliance with WTO obligations" http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1745.

We trust that you will find this information helpful in your deliberations and we would be pleased to discuss further and in more detail with any WTO Member interested in getting a fuller and clearer account of the experience to date with the Doha Paragraph 6 system as enacted by Canada.

Sincerely,

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FOR ADDITIONAL INFORMATION:

CAMR page of the Canadian HIV/AIDS Legal Network:
www.aidslaw.ca/camr

Video by the Grandmothers to Grandmothers Campaign:
http://www.youtube.com/watch?v=FmxOU24mXHU

Video by the Canadian HIV/AIDS Legal Network:
http://www.youtube.com/watch?v=bG7_tQir0-s

Video by Universities Allied for Essential Medicines:
http://www.youtube.com/watch?v=zZZJn8rNXKI