CANADIAN HIV•AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH•SIDA

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MÉDECINS SANS FRONTIÈRES

Oxfam Canada

Interagency Coalition on AIDS and Development | Coalition interagence sida et développement

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September 23, 2003

Hon. Allan Rock
Minister of Industry
Office of the Minister
235 Queen Street East
Ottawa, ON
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Dear Minister:

**Re: Patent Act amendments and the export of Canadian-made generic medicines**

We write to you, as representatives of Canadian civil society organizations, to request that the Government of Canada take a simple, yet significant, step to demonstrate leadership and to enhance our country's response to the HIV/AIDS pandemic and other global health challenges: we ask that you amend Canada's *Patent Act* to facilitate the export of Canadian-made generic medicines to developing countries in need. We also respectfully request the opportunity to meet with you to discuss our proposal in more detail.

***Recent developments at the World Trade Organization***

As you know, for several years a worldwide debate has been occurring over the impact on access to affordable medicines in developing countries of stringent provisions on intellectual property protection in international treaties such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization. In November 2001, at the 4th WTO Ministerial Conference in Doha in November 2001, WTO members unanimously adopted a "Declaration on the TRIPS Agreement and Public Health". In that Declaration, they expressly stated that:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.
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> In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

In Paragraph 6 of the same Declaration, WTO Members recognized that countries "with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." This problem arose because of the restriction, under Article 31(f) of the TRIPS Agreement, on the use of compulsory licensing in countries with manufacturing capacity to authorize the production of generics for export to countries lacking sufficient capacity. WTO Members instructed the Council for TRIPS to find an expeditious solution to this problem by the end of 2002.

Since the Declaration was adopted in Doha, it has taken over 21 months for WTO members to agree on a "solution" as called for by the Ministerial Conference. On 30 August 2003, WTO Members adopted an agreement ostensibly aimed at solving this problem, so as to make it possible for countries lacking domestic manufacturing capacity to import generic medicines produced elsewhere under compulsory license.

We welcome the fact that, despite the efforts of some countries, this agreement is not limited in its application to only specific diseases, nor is it restricted to emergency situations only. However, as you will be aware, numerous humanitarian and other non-governmental organizations have been critical of this deal for imposing various restrictions on the use of compulsory licensing not faced by countries with developed manufacturing capacity in the pharmaceutical sector. In our view, the "solution" is burdened with procedural obstacles and is open to abuse by those who wish to limit or prevent countries from availing themselves of it in order to access imports of less expensive generic medicines. Notwithstanding the flaws of this solution, it is now up to all WTO Members, in the spirit of the Doha Declaration, to ensure that developing countries in need of more affordable drugs are able to use it with maximum flexibility and effect.

To this end, countries such as Canada have a contribution to make, as the home to potential suppliers of lower-cost medicines. We have a well-developed generic pharmaceutical sector, with the capacity to produce medicines urgently needed in many developing countries. We note that the Canadian General Pharmaceutical Association has consistently stated that its member companies wish to produce generic formulations of medicines for export to developing countries. Indeed, the CGPA has recently written to your colleague, the Hon. Pierre Pettigrew, Minister for International Trade, reiterating its desire to meet this global demand, following the announcement of the WTO agreement to relax the TRIPS restrictions on generic exports.

Yet, because of the state of Canadian law, the resources of this sector cannot currently be marshalled to respond to this global need. As you know, our *Patent Act* currently makes no provision for granting legal authorization for the manufacture in Canada, for export, of a generic version of a medicine protected by patent in Canada. (The exceptions are the narrowly circumscribed provisions on "government use" and the remedies for abuse of patent rights, neither of which is amenable to large-scale production of generics for export.) Without such authorization, any such manufacture would constitute an infringement of the patentee's exclusive rights and result in legal liability.

**We call upon the Government of Canada to show leadership in the response to the global crises of HIV/AIDS, tuberculosis and malaria, and other health challenges facing developing countries, by immediately amending the *Patent Act* to facilitate the production in Canada of generic medicines for export to developing countries.**

***Proposed amendment to the Patent Act***

In our view, by far the most appropriate way to do this would be take advantage of the flexibility already offered by the TRIPS Agreement. Under Article 30 of the TRIPS Agreement, WTO Members may, in their domestic legislation, provide for "limited exceptions" to the exclusive patent rights that the TRIPS Agreement requires Members to recognize. Article 30 states:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of a patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

It would, therefore, be open to Canada to simply amend the *Patent Act* to insert a provision creating the following "limited exception" to the exclusive rights of a patentee under Canadian law:

> *Manufacturing of a pharmaceutical product by a person other than the patentee shall be allowed if the pharmaceutical product is intended for export to a country in which, in respect of that product, either a compulsory license has been issued or a patent is not in force.*

An accompanying amendment should make it clear, in line with the wording of the decision adopted by the WTO General Council on 30 August 2003, that the term "pharmaceutical product" means "any patented product, or product manufactured through a patented process, of the pharmaceutical sector" and includes "active ingredients necessary for its manufacture and diagnostic kits needed for its use."

Such an amendment would be the most straightforward manner in which to facilitate the production of Canadian generics for export to respond to the need for more affordable medicines in many developing countries. The recent agreement at the WTO on

overcoming generic export restrictions found in Article 31(f) of the TRIPS Agreement does not in any way preclude Canada from adopting an amendment in the form we have proposed, which would show leadership among countries by illustrating the flexibility that can also be found in Article 30 of the TRIPS Agreement. Furthermore, such an approach does not affect in any way the market exclusivity within Canada of pharmaceutical patentees, and appropriately allows the question of reasonable compensation for patentees to be determined in accordance with the laws of the country importing the medicines. Finally, it is simple, direct and fair, and has not only attracted the support of dozens of developing country members of the WTO, but also that of humanitarian organizations directly engaged in delivering medicines on the ground in developing countries and of the World Health Organization.

We wish to point out that not only does Canada have a moral duty to take such a simple step to prevent unnecessary death and suffering, but amending our *Patent Act* to remove restrictions on generic exports is also consistent with Canada's duties under international human rights law.

Canada is a State Party to the *International Covenant on Economic, Social and Cultural Rights.* Canada has, therefore, recognized the human "right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (Article 12). Furthermore, Canada has legally bound itself to take steps to fully realize this right, including "those necessary for… the prevention, treatment and control of epidemic, endemic, … and other diseases" (Article 12).

We note as well that Canada has also assumed the legal obligation, under the *Covenant* (Article 2) "to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures." Amending our *Patent Act* as we have proposed is in line with our legal obligations to take legislative and other measures as part of Canada's international assistance and cooperation in protecting, promoting and fulfilling the human right to health.

The situation facing many developing countries is dire already, and worsening by the day. We trust you share our sense of urgency and our wish to ensure that Canada does whatever it can to respond quickly and effectively to the global crises of HIV/AIDS, tuberculosis and malaria, and the many other health needs of poor people and countries. Two years ago, Canada joined the other members of the United Nations in adopting the General Assembly's "Declaration of Commitment on HIV/AIDS", in which it pledged to take action to respond to the global AIDS crisis. At yesterday's session of the UN General Assembly to discuss progress made in implementing that Declaration, Canada again promised action and reiterated its commitment. It is time to take this small, but significant, step in helping sick people get access to affordable medicines.

**We respectfully request the opportunity to meet with you and your staff to discuss further this pressing matter.** We also offer our assistance and support to the Government of Canada in amending Canadian law to support the realization of human rights of those desperately in need of more affordable, life-saving medicines.

We look forward to hearing from you at your earliest convenience and would be pleased to meet with you and your colleagues as soon as possible.

Sincerely,


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cc: Rt. Hon. Jean Chrétien
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