



October 25, 2001

AN OPEN LETTER TO ALL MEMBERS OF PARLIAMENT

Dear Honourable Members:

**Re: Patents and generic drugs in the WTO Ministerial Declaration**

As humanitarian, human rights, and development organisations actively engaged in the Canadian and international responses to the global HIV/AIDS pandemic, we wish to raise with you our grave concerns about current discussions at the World Trade Organisation (WTO) regarding the Agreement on Trade-Related Aspects of Intellectual Property Rights ("**the TRIPS Agreement**"), and Canada's role in those discussions.

We have also written to the Prime Minister and other key ministers with these concerns.<sup>1</sup> We respectfully urge you to raise these matters of fundamental importance with your colleagues and with the government, including in the House of Commons.

As you are aware, poor countries desperately need to make medicines for deadly diseases such as HIV/AIDS, tuberculosis, and malaria more affordable. One-third of the world's people lack access to the most basic essential drugs. In the poorest parts of Africa and Asia, this figure is one-half. A number of new medicines vital for the survival of millions are already too costly for the vast majority of people in poor countries. Strictly defending pharmaceutical companies' monopolies through patents is already a barrier in many places to accessing affordable medicines.

But the TRIPS Agreement requires all WTO countries to adopt enhanced patent protections for medicines, standards derived from wealthy developed countries that may not be appropriate for developing and least-developed countries bearing the brunt of the global HIV/AIDS and tuberculosis pandemics.

And unless action is taken now, the situation could get even worse in the years to come, as the TRIPS Agreement will apply to an even greater number of poor countries currently exempt. This will have

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<sup>1</sup> A copy of that letter, and a detailed backgrounder explaining why Canada must act, can be found at [www.aidslaw.ca](http://www.aidslaw.ca) or [www.msf.ca/access/index.htm](http://www.msf.ca/access/index.htm).

further serious consequences for the availability of new essential medicines, at a time when tens of millions of people in poor countries are dying of AIDS and other diseases. This is why it is so critical that the WTO countries address the impact of this agreement to ensure that it does not hinder poor countries' access to affordable medicines.

**The 4<sup>th</sup> WTO Ministerial Conference is scheduled for November 9-13, 2001 in Doha, Qatar. For the reasons set out below and in the enclosed material, it is crucial that the WTO Ministerial Conference issue a declaration that affirms, without reservation, that the TRIPS Agreement shall not be interpreted or used in a manner that prevents countries from taking measures to protect public health or the human right to health.**

**We are therefore very concerned that, to date, Canada appears to be playing a less than constructive role in ongoing negotiations at the WTO regarding this issue.**

**A group of 60 developing countries from Africa, Asia and Latin America have put forward considered, reasonable proposals for the contents of a Ministerial Declaration on the TRIPS Agreement, access to medicines and public health.<sup>2</sup> They are seeking a declaration that affirms that nothing in the TRIPS Agreement shall prevent countries from taking measures to protect public health. (The developing countries' proposal is attached.)**

**However, rather than support this proposal, Canada has joined a small handful of wealthy countries in putting forward a vague counter-proposal that does little more than re-state what is already in the TRIPS Agreement. That counter-proposal fails to address most of the key needs identified by developing countries. One of its key omissions is that it fails to expressly affirm that nothing in the Agreement shall prevent WTO members from taking measures to protect public health.**

We have urged the Canadian government to fully support the proposals by developing countries. Government officials have repeatedly asserted that TRIPS provides adequate flexibility for developing countries to make medicines more affordable for such needs as the HIV/AIDS crisis. If the government truly believes this, then there is no reason for Canada to balk at endorsing a Ministerial Declaration as proposed by the large group of developing countries.

We do not oppose patents *per se*. Real innovation deserves to be recognized, protected and encouraged. But patents, and the high profits they have generated for pharmaceutical companies, are not ends in themselves. Patents are public policy tools, means to the end of benefiting society as a whole. The very purpose of patent protection is defeated if the system prevents those benefits from reaching the vast majority of the world's people who need them. Patent policy must acceptably balance public and private interests: when the strict enforcement of patent rights endangers the public health, governments are not only entitled to limit patent monopolies, but have a legal and moral duty to do so.

Indeed, the Hon. Pierre Pettigrew (Minister for International Trade) recently reminded Canadians: "Developing countries must prepare their societies for open trade. The way they can do this is through domestic reforms, such as...adopting policies that ensure the benefits are shared throughout society."<sup>3</sup>

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<sup>2</sup> Ministerial declaration on the TRIPS Agreement and Public Health: Proposal from a group of developing countries. WTO Document IP/C/W312, WT/GC/W/450, presented 19 September 2001 to Council for TRIPS, released publicly 4 October 2001 (available via [www.wto.org](http://www.wto.org)). It should be noted that the Government of Norway is supporting the developing countries' proposals.

<sup>3</sup> Hon. Pierre Pettigrew. "How trade will save the world." *The Globe & Mail*, 11 October 2001: A19.

At the UN's Special Session on HIV/AIDS held earlier this year, all the countries of the world declared their commitment to responding to this global health crisis. Canada has endorsed international agreements that recognize every person's human right to enjoy the benefits of scientific progress and to the highest attainable standard of health.

Yet particularly with regard to medicines, access to innovations is unequally distributed in the world. Developing countries, which have 75% of the world's population, account for less than 10% of the global pharmaceutical market. Sub-Saharan Africa, the region currently most devastated by the HIV/AIDS epidemic, represents little more than 1% of the total global sales of medicines.

Allowing developing countries to put reasonable limits on the patent rights of pharmaceutical companies (the world's mo

## ANNEX

**PROPOSAL BY THE AFRICAN GROUP, BANGLADESH, BARBADOS, BOLIVIA, BRAZIL, CUBA, DOMINICAN REPUBLIC, ECUADOR, HAITI, HONDURAS, INDIA, INDONESIA, JAMAICA, PAKISTAN, PARAGUAY, PHILIPPINES, PERU, SRI LANKA, THAILAND AND VENEZUELA**

IP/C/W/312  
WT/GC/W/450  
4 October 2001  
(01-4803)

General Council  
Council for Trade-Related Aspects of Intellectual Property Rights

During the special discussion of the TRIPS Council on 19 September 2001, the following proposal was communicated to the Secretariat for circulation among Members of the Council by Zimbabwe on behalf of the above-mentioned delegations. When submitting the text, the delegations in question indicated that this was without prejudice to individual country positions and their right to submit additional proposals.

### **Ministerial declaration on the TRIPS agreement and public health**

Ministers,

*affirming* that the protection and promotion of public health and nutrition is a fundamental obligation and prerogative of the State and that Members retain their sovereign power in this regard;

*realizing* that the inability of large segments of the population to obtain medicines and treatment at prices they can afford threatens the vital interest of States in protecting and promoting public welfare, preserving law and order, and maintaining social cohesion;

*discharging* the obligation to protect and promote the fundamental human rights to life and the enjoyment of the highest attainable standard of physical and mental health, including the prevention, treatment and control of epidemic, endemic, occupational and other diseases and the creation of conditions which would assure to all medical service and medical attention in the event of sickness, as affirmed in the International Covenant on Economic, Social and Cultural Rights;

*cognizant* of the concerns expressed by non-governmental organizations, public health advocates and the worldwide public regarding potential implications of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) on the availability and affordability of needed medicines and other healthcare products;

*concerned* about the lack of adequate research and development on medicines for the prevention and treatment of diseases predominantly affecting people in developing and least-developed countries;  
*emphasizing* that the protection of intellectual property rights, in particular patent protection, should encourage the development of new medicines and the international transfer of and access to technology to promote the development and maintenance of sustainable domestic manufacturing capacities for medicines and other healthcare products;

*recognizing* that in implementing domestic health policies, especially as regards the availability and affordability of medicines and other healthcare products, both the research-based and the generics

pharmaceutical industries have important and complementary roles to perform, particularly in developing and least-developed countries;

*stressing* the importance of the participation of public health officials in discussions and decision-making on intellectual property rules that may have an effect on the availability of and access to healthcare products;

*recalling* the Preamble of the TRIPS Agreement, which, among others, prescribes that measures and procedures to enforce intellectual property rights should not themselves become barriers to legitimate trade and recognizes the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

*recalling further* Article XI:2 of the Marrakesh Agreement Establishing the World Trade Organization and the Decision on Measures in Favour of Least-Developed Countries adopted on 15 December 1993;

*reaffirming* the General Council decision of 7-8 February 2000 (WT/GC/M/53) that the mandated review of the TRIPS Agreement, among others, should address the impact of the agreement on the trade and development prospects of developing countries;

*acknowledging* the vulnerability of developing and least-developed country Members to the imposition or the threat of imposition of sanctions and to the prospect of being deprived of incentives or other benefits, including those imposed or offered, as the case may be, beyond the framework of the WTO;

*recognizing* that challenges within the WTO dispute settlement system may in themselves inhibit or curtail the ability of Members to formulate and implement measures to protect and promote public health;

*noting* the ongoing examination by the Council for TRIPS on the scope and modalities for the possible application of subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 to the settlement of disputes under the TRIPS Agreement;

*recognizing* that public health crises of unprecedented consequences, of which HIV/AIDS is a most dramatic example, afflict developing countries;

*anticipating* that drawing attention to and reaffirming the context of the TRIPS Agreement and certain provisions thereof as an initial concrete step will further encourage Members, particularly developing and least-developed country Members, towards considering every possible policy option for the protection and promotion of public health;

*emphasizing* the fundamental importance of the objectives and principles of the TRIPS Agreement.

**Ministers declare that:**

1. Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health.
2. Each Member retains the right to establish its own policy and rules regarding the exhaustion of intellectual property rights.

3. Each Member has the right to allow other use of the subject-matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, and to determine the grounds upon which such use is allowed.
4. In the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, Members may grant compulsory licences without prior efforts on the part of the user to obtain authorization from the right holder.
5. A compulsory licence issued by a Member may be given effect by another Member. Such other Member may authorize a supplier within its territory to make and export the product covered by the licence predominantly for the supply of the domestic market of the Member granting the licence. Production and export under these conditions do not infringe the rights of the patent holder.
6. Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) of Article 31 of the TRIPS Agreement where use of the subject-matter of a patent is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.
7. Nothing in the TRIPS Agreement shall prevent Members from establishing or maintaining marketing approval procedures for generic medicines and other healthcare products, or applying summary or abbreviated marketing approval procedures based on marketing approvals granted earlier for equivalent products.
8. Nothing in the TRIPS Agreement shall prevent Members from disclosing or using information held by its authorities or the patent holder where it is so required for reasons of public interest, including where such disclosure or use is necessary to implement effectively any compulsory licences or other measures adopted by public authorities in the public interest.
9. Under Article 30 of the TRIPS Agreement, Members may, among others, authorize the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing Members.
10. Each Member shall, within or beyond the framework of the WTO, refrain from imposing or threatening to impose sanctions and refrain from employing the grant of incentives or other benefits in a manner which could curtail the ability of developing and least-developed country Members to avail themselves of every possible policy option to protect and promote public health.
11. Members shall exercise utmost restraint in initiating and pursuing dispute settlement proceedings relating to measures adopted or implemented, particularly by developing and least-developed country Members, to protect and promote public health.
12. In its examination of the scope and modalities for the possible application of subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 to the settlement of disputes under the TRIPS Agreement, and without prejudice to recommendations that the Council for TRIPS may adopt and submit to the Ministerial Conference on other relevant aspects, in no event shall such subparagraphs be rendered applicable to measures adopted and implemented by Members, particularly developing and least-developed country Members, to protect and promote public health.
13. In view of the special needs and requirements of developing and least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, the transition period provided for their benefit under Articles 65.4 and 66.1 of the TRIPS Agreement shall be extended for another period of five (5) years from the expiration of the

transition periods provided thereunder, particularly in respect of the obligation to render available patent protection on products or processes relating to public health, without prejudice to further extensions.

14. The TRIPS Council shall monitor and evaluate on an ongoing basis, in collaboration with relevant international organizations, the effects of the TRIPS Agreement on health, with particular emphasis on access to medicines and research and development on medicines for the prevention and treatment of diseases predominantly affecting people in developing and least-developed countries.

Note:

(1) “Other use” refers to use other than that allowed under Article 30 of the TRIPS Agreement.