October 25, 2001

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Dear Prime Minister and Honourable Ministers:

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 regarding the Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement"), and Canada's role in those discussions.

For the reasons set out below and in the enclosed material, it is crucial that the upcoming WTO Ministerial Conference declare, 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[1] for the contents of a Ministerial Declaration on the TRIPS Agreement, access to medicines and public health to be adopted at the forthcoming WTO Ministerial Conference scheduled for November 9-13, 2001.

However, rather than support this proposal, Canada 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.[2] 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 urge the Canadian government to fully support the proposals by developing countries. Canadian 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 Canada truly believes this, then there is no reason for Canada to balk at endorsing a Ministerial Declaration that expressly states that the TRIPS Agreement shall not be interpreted or applied so as prevent countries from taking measures to protect public health and the human right to health.

Canada can and should play a crucial role at the WTO to ensure an interpretation of the TRIPS Agreement that helps developing countries make medicines more affordable. **We hope to shortly see Canada's public support for the developing countries' proposals for a clear, pro-health Ministerial Declaration at the upcoming WTO meeting in November.**

We look forward to your responses to this letter. We would be pleased to meet with you or your colleagues in the coming days before the WTO Ministerial Conference to discuss these issues in more detail.

Sincerely,

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[1] 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). It should be noted that the Government of Norway is supporting the developing countries' proposals.

[2] Preambular language for ministerial declaration: Proposal from a group of developed countries. WTO Document IP/C/W/313, presented 19 September 2001 to the Council for TRIPS, released publicly 4 October 2001 (available via www.wto.org) (contribution from Australia, Canada, Japan, Switzerland & the United States). A second "non-paper" circulated by a group of developing countries (Canada, the Czech Republic, Japan, New Zealand, Switzerland & the United States), containing proposals for the operative provisions of the declaration (and not just preambular language) was presented at the Council for TRIPS on 21 September 2001, and has been obtained by civil society groups, but has yet to be released publicly by the WTO.

Enclosed:

THE CRISIS IN ACCESS TO ESSENTIAL MEDICINES: WHY CANADA MUST ACT
Appendix prepared for the Rt. Hon. Jean Chrétien, Hon. Pierre Pettigrew, Hon. Paul Martin, Hon. Paul Martin, Hon. Brian Tobin, Hon. John Manley, Hon. Allan Rock, and Hon. Maria Minna.
By Médecins Sans Frontières/Doctors Without Borders Canada, Canadian HIV/AIDS Legal Network, Oxfam Canada, Interagency Coalition on AIDS and Development, Canadian Treatment Action Council, Canadian Council for International Co-operation. October 25, 2001.

ANNEX 1:

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

ANNEX 2:

PROPOSAL FROM A GROUP OF DEVELOPED COUNTRIES

PART I -- PROPOSAL FOR PREAMBULAR LANGUAGE FOR MINISTERIAL DECLARATION, IP/C/W/313, 4 October 2001, (01-4779). Council for Trade-Related Aspects of Intellectual Property Rights, Preambular language for ministerial declaration. Contribution from Australia, Canada, Japan, Switzerland and the United States.

PART II -- PARTIAL PROPOSAL FOR OPERATIVE PROVISIONS OF A MINISTERIAL DECLARATION, Non Paper. (Proposal presented 21 September 2001 at the Council for TRIPS). Contribution from Canada, the Czech Republic, Japan, New Zealand, Switzerland and the United States.

Cc: His Excellency Sergio Marchi, Permanent Representative to the World Trade Organization

Mr. Don Stephenson, Director General, Trade Policy Bureau II (Services, Investment & Intellectual Property Bureau), DFAIT

Ms. Catherine Dickson, Director, Information & Technology Trade Policy Division, Trade Policy II Bureau (Services, Investment & Intellectual Property Division), DFAIT

Excellencies from African countries' High Commissions and Embassies to Ottawa

THE CRISIS IN ACCESS TO ESSENTIAL MEDICINES: WHY CANADA MUST ACT

Appendix prepared for the Rt. Hon. Jean Chrétien, Hon. Pierre Pettigrew, Hon. Paul Martin, Hon. Paul Martin, Hon. Brian Tobin, Hon. John Manley, Hon. Allan Rock, and Hon. Maria Minna.

By Médecins Sans Frontières/Doctors Without Borders Canada, Canadian HIV/AIDS Legal Network, Oxfam Canada, Interagency Coalition on AIDS an d Development, Canadian Treatment Action Council, Canadian Council for International Co-operation.

October 25, 2001.

1. The crisis

As the entire world is now well aware, poor countries desperately need to make medicines for deadly diseases such as HIV/AIDS, tuberculosis, malaria and others more affordable. The World Health Organisation and UNAIDS estimate that, in the year 2000 alone, roughly 3 million people died of AIDS, 2 million died of tuberculosis, and 1-2 million died from malaria. Poor countries see 95% of tuberculosis cases, and 98% of tuberculosis deaths. Over 70% of the world's cases of HIV/AIDS are in sub-Saharan Africa, home to many of the world's poorest countries. Over 8000 people continue to die of AIDS every day around the world.

Many of these premature deaths, and the incredible human suffering and damage to economic development they represent, could have been prevented. But medicines that are vital for the survival of millions are too costly for the vast majority of people in poor countries, and for the governments of many poor countries. 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 rises to one-half.

There is no doubt that the world faces a health crisis of unprecedented proportions, in which millions of people are dying because they are poor, when it is easily within our collective means to mount an effective, sustained response. The Director General of the World Health Organisation, Dr. Gro Harlem Brundtland, has said bluntly: "Let us be frank about it: essential and life-saving drugs exist while millions and millions of people cannot afford them. That amounts to a moral problem, a political problem and a problem of credibility for the global market system."[3]

Canada has committed itself repeatedly -- most recently on the occasion of the UN General Assembly Special Session on HIV/AIDS in June 2001 -- to be part of the solution to this problem. We ask that Canada live up to these commitments, including in its positions and contributions in international trade discussions, because it can no longer be denied that international trade agreements do have an impact on health and human rights.

2. The TRIPS Agreement and strict patent rights are (but need not be) part of the problem

As has been repeatedly pointed out, there are many factors that influence the availability and affordability of medicines needed in developing and least-developed countries. There is no doubt that sustained action is required on many fronts: building health care infrastructures; increasing research and development into major diseases in poor countries; addressing domestic taxes, tariffs and mark-ups on medicines; ensuring rational prescribing of drugs; etc.

[3] Dr. Gro Harlem Brundtland, Director-General, World Health Organization. "Towards a strategic agenda for the WHO Secretariat: Statement by the Director-General to the Executive Board at its 105th Session," 24 January 2000.

But, as Canada[4] and many others have recognized, including at the WTO, there can also be no doubt that one of the key barriers to affordable medicines is price. And one of the most important factors affecting the price of drugs is the existence of patents and the presence or absence of competition, including from generic drugs.

Patents create monopolies on medicines, excluding competition on the market (for a minimum of 20 years under the TRIPS Agreement) and allowing patent-holders to charge whatever price they anticipate will maximize profit. Without public intervention of various kinds to mitigate the effects of monopoly pricing and practices, there is no means of ensuring the public interest is protected.

As a result of the WTO's TRIPS Agreement, intellectual property policy is no longer solely a matter of domestic concern, to be shaped according to the needs and priorities of that country. All WTO member countries are now obliged to respect intellectual property standards derived from those of wealthy industrialized countries, even if these are not necessarily appropriate in light of the level of development or other local circumstances.

All WTO member countries are required to implement the minimum requirements set out in the TRIPS Agreement in their domestic legislation. Developed countries were required to comply by January 1, 1995, developing countries by January 1, 2000, and least-developed countries by January 1, 2006.[5] Some countries, often as a result of pressure from developed countries such as the United States, have already brought their domestic legislation into conformity with the TRIPS Agreement, well ahead of the required deadline.[6]

We do not oppose patents per se, and recognize that real innovation deserves to be recognized, protected and encouraged. But patents, and the high profits they have generated for pharmaceutical companies, are not an end in themselves. Patents are public policy tools, means to the end of benefiting society as a whole. The very purpose of intellectual property 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 damages the public interest, governments are not only entitled to limit patent monopolies, but have a legal and moral duty to do so where this is necessary to protect the public health and individuals' human right to the highest attainable standard of health.

Some claim that patents are not significant barriers.[7] The experience of medical personnel in the field shows differently, reinforcing why governments need room to prevent and/or limit the adverse effects of

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[4] Statement of Canada at WTO Council for TRIPS Special Discussion on Intellectual Property and Access to Medicines, Geneva, 18-22 June 2001. WTO Document IP/C/M3, page 60.

[5] The agreement contemplates that least-developed countries may be able to obtain an extension beyond this point, "upon duly motivated request" and with the consent of the WTO's Council for TRIPS. How such requests might be received remains to be seen, although the unwillingness shown to date by developed countries to accept proposals maximizing the flexibility within the Agreement is cause for concern.

[6] In some cases, countries have introduced "TRIPS-plus" legislation going beyond what is required under the TRIPS Agreement and further limiting government policy tools aimed at public interest objectives such as increasing access to affordable medicines for HIV/AIDS, tuberculosis, malaria and other fatal diseases.

[7]For example, a recent study purported to show that patents "are not a major barrier to treatment access in and of themselves": A Attaran & L Gillespie-White. Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? *Journal of the American Medical Association* 2001; 286: 1886-1892. However, the study has

exclusive patent rights. Two examples drawn from the current situation facing doctors with Médecins Sans Frontières (MSF) in Africa illustrate how strictly interpreted patent regimes directly prevent poor people from accessing life-saving medicines.

· In South Africa, MSF runs an AIDS project in Khayelitsha, a township of 400,000 people outside Cape Town. About 25% of the population is HIV-positive and an estimated 5000 people currently need treatment with anti-retroviral drugs. These drugs are priced at more than US$2300 to treat one adult for one year. People in Khayelitsha cannot afford this. MSF has started treatment with anti-retroviral therapy in the township, but cannot take advantage of generic manufacturers' offer of three-drug HIV therapy for about US$300/year because of patents held by multinational pharmaceutical companies. At these drastically lower prices, MSF could afford to treat seven times as many people with the same limited funds. While many South Africans in need could not afford even $300/year, there is no question that this much lower price would bring effective treatment within the affordable range for many more people, who currently live (and die) with the knowledge that, if they could only pay the high price, they could purchase their lives.

· In Kenya, Pfizer Inc. sells its patented fluconazole (Diflucan®) at US$6.40 per 200-mg tablet. Generic equivalents are available for as little as US$0.10 per tablet from reputable companies such as CIPLA, an Indian generic drugs manufacturer. Fluconazole is an essential drug for treating cryptococcal meningitis, which affects up to 1 in 4 people with HIV/AIDS in some countries. Without treatment, people usually die of this disease in less than a month. Pfizer has announced a drug donation program, but Kenya is not an eligible country. Pfizer's patent runs until April 2002 (at least). During that time, unless generic fluconazole is made available by limiting Pfizer's exclusive patent rights, tens of thousands of people will die from a treatable illness. This example illustrates one of the many ways in which an effective, comprehensive, sustained response to the global HIV/AIDS epidemic cannot rely solely on charity (limited in time and to only certain target countries) from multinational pharmaceutical companies. Rather, it must include policy tools for sovereign countries to shape their own domestic policy so as to ensure ongoing access to more affordable medicines.

It is true that *some* existing medicines to treat *some* aspects of HIV disease are currently not under patent in *some* countries -- creating a window of opportunity for treatment with generics in some cases, where these are available and affordable. This does not mean that strict patent rights are somehow not a problem. Rather, patent coverage is still a major barrier to access to HIV/AIDS treatments in many of the countries where it is most desperately needed.

Indeed, Canada has already publicly recognized that most HIV/AIDS therapies are still covered by patents.[8] Although the situation varies from country to country, such drugs are clearly patented in many of the African countries most affected by the HIV/AIDS crisis. A critical analysis of figures from an August 2001 survey done by the U.S.-based Pharmaceutical Research and Manufacturers Association (PhRMA) itself shows that the 29 African countries that have patents on anti-retroviral drugs have 71% of the population of the African continent and 72% of the HIV-positive people on the continent. The figures also show that the country with the highest number of patents on anti-retroviral drugs (15) is

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been widely criticized for failing to admit that many of the cheapest, most easily delivered combinations of drugs needed to effectively treat HIV disease are blocked by patents in many African countries, leaving those doctors and patients who might have some possibility of accessing treatment with sub-optimal treatment options, which in itself increases the risk of drug resistance developing, worsening an already dire situation.

[8] Statement of Canada at WTO Council for TRIPS Special Discussion on Intellectual Property and Access to Medicines, Geneva, 18-22 June 2001. WTO Document IP/C/M3, page 60.

South Africa, the country with the single largest absolute number of people with HIV of any country in the world, at over 4.2 million people.[9]

Furthermore, an analysis of the data from PhRMA's own survey indicates that the medicines which are under patent in more than two dozen African countries are all or nearly all of the very therapy combinations that are (a) cheap to produce, and (b) available with fairly simple twice daily dosing regimens. Both of these are important treatment considerations in settings with limited resources and in those areas of developing countries that have limited health infrastructure.

These and numerous other examples can leave no doubt that, in many circumstances, strictly defended pharmaceutical company patents do indeed represent a key barrier to accessing affordable medicines. In some cases, the high monopoly price of drugs -- sustained by exclusive patent rights -- is the only significant barrier for many people.

TRIPS creates additional barriers

Unless action is taken now, the situation will get even worse in the years to come. The TRIPS Agreement's requirements for enhanced patent protection will come into force for a greater number of even poorer countries (and countries which are getting poorer as a result of the global HIV/AIDS and tuberculosis pandemics), at the very time that those countries face increasingly devastating public health crises that may result in the deaths of one-quarter to one-half of their population from treatable diseases.

Furthermore, now that TRIPS requires global patent protection (for a minimum of 20 years) on pharmaceutical products, patents will be available in more countries on all new medicines that are developed. Advances in treatment for HIV/AIDS, TB and malaria in the coming years will likely range from simpler regimens for combinations of existing drugs to new chemical compounds. Both are needed in developing countries bearing the brunt of the world's epidemics with limited and diminishing resources. But they will be unaffordable to most of the world's people with HIV/AIDS and other seriously neglected communicable diseases, unless governments implement strong policies to promote the availability of cheaper quality medicines, such as compulsory licensing to ensure competition from generic products, parallel imports of patented medicines at cheapest world market prices, mechanisms to control excessive pricing by patent-holders, etc. The TRIPS Agreement cannot be allowed to stand in the way of responding to a crisis of health and human rights.

3. The need for a clear, pro-health Ministerial Declaration on the TRIPS Agreement

This is why it is so critical that the WTO countries address the impact of this agreement to ensure that neither the text of the Agreement, nor its cynical manipulation by some countries and large pharmaceutical companies, are allowed to hinder poor countries' efforts to improve access to affordable medicines. Under the Agreement establishing the WTO, the biennial Ministerial Council is the highest decision-making body with the authority to adopt interpretations of the WTO trade agreements.[10] A Ministerial Declaration at the upcoming Ministerial Conference in Doha, Qatar could have a significant impact in the years ahead on the interpretation and application of the TRIPS Agreement.

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[9] This analysis of the PhRMA survey data is taken from: J Love & M Palmedo - Consumer Project on Technology. "Where are the sub-Saharan patents filed, in terms of population, infection rates and income?" 6 October 2001 (draft), on-line at: http://lists.essential.org/pipermail/ip-health/2001-October/002002.html.

[10] Agreement Establishing the World Trade Organization (1994), Article IX(2).

The experience to date with the TRIPS Agreement -- both in its interpretation by WTO panels and the Appellate Body, and in its political use by developed countries -- gives us ample evidence of the need for a clear Ministerial Declaration that will have this effect. Some examples help illustrate this point.

The Canadian experience: WTO disputes over pharmaceutical patents

Canada itself has already faced two separate challenges at the WTO to provisions in its *Patent Act*, by countries alleging Canada was in breach of its TRIPS obligations. In both cases, the focus was on pharmaceutical patents. In the *Patent Term* case, Canada lost the dispute, and was forced to amend its legislation as a result, extending the patent term on tens of thousands of patents, even though this meant retroactively applying the TRIPS Agreement's requirements to patents that had been issued before Canada became subject to the Agreement.[11]

In the *Generic Medicines* case, [12] Canada successfully defended one important aspect of its legislation (the "early working" or "Bolar" exception, which many other developed countries also have). But the WTO Panel rejected Canada's defence of the "stockpiling" exception -- which preserved patent-holders' market monopolies during the 20 year patent term but allowed generic manufacturers to stockpile their product in the last 6 months of this term, so as to enter the market as soon as possible after patent expiry, making cheaper generic medicines available to consumers and to private and government insurers as soon as possible.

Of particular concern was that the WTO Panel rejected Canada's defence of this stockpiling provision as a "limited exception" to exclusive patent rights that was permissible under the TRIPS Agreement (Article 30). Canada appealed to the foundational provisions in the TRIPS Agreement setting out its "objectives" (Article 7) and its "principles" (Article 8). Article 7 recognizes that the protection of intellectual property rights should contribute to innovation and the dissemination of technology that benefits both producers and users of knowledge, "in a manner conducive to social and economic welfare, and to a balance of rights and obligations." Article 8 states that member countries may "adopt measures necessary to protect public health… provided that such measures are consistent with the provisions of this Agreement."

But the WTO Panel failed to interpret the "limited exceptions" article of the TRIPS Agreement in the light of these over-arching provisions, in complete disregard of basic international legal principles of treaty interpretation. In fact, Canada's "public interest" argument received no attention by the WTO Panel.

Canada's experience to date -- and, along with India, Canada has the most experience to date of any country of arguing pharmaceutical patent cases before the WTO -- is not encouraging. These decisions, and others invalidating environmental or other public interest regulations, demonstrate an overall hostility, in the interpretation of WTO agreements, to considering any other obligations on governments to protect the public good. They highlight the fundamental importance of ensuring that the TRIPS Agreement is interpreted correctly, in line with its stated objectives and principles, and in a fashion consistent with member countries' superseding obligations under international law to respect, protect and fulfil human rights. Those rights include the right to the highest attainable standard of health and the right

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[11] *Canada - Term of Patent Protection* ("the Patent Term" case), Report of the Apellate Body, WT/DS170/AB/R, 18 September 2000; Report of the Panel, WT/DS170/R, 5 May 2000 (available via www.wto.org).

[12] *Canada - Patent Protection of Pharmaceutical Products* ("the Generic Medicines case"), Report of the Panel, WT/DS114/R, 17 March 2000 (available via www.wto.org).

to enjoy the benefits of scientific progress (Articles 25 & 27 of the *Universal Declaration of Human Rights*, Articles 12 & 15 of the *International Covenant on Economic, Social & Cultural Rights*).

Given the authority of the Ministerial Conference over the interpretation of WTO agreements, and the statements by numerous governments (including Canada) that they wish to ensure that the benefits of globalization and trade liberalization are shared, the imperative to issue a clear declaration to this effect is clear.

The South African and Brazilian experiences

As you are certainly aware, narrow interpretations of the TRIPS Agreement have been invoked in efforts to block developing countries from implementing legislation aimed at improving access to affordable medicines to treat HIV/AIDS and other illnesses, even though this legislation is TRIPS-compliant by all reasonable standards. When South Africa, which faces spiralling rates of HIV infection and AIDS as a leading cause of death, introduced legislative measures aimed at making medicines more affordable, the proprietary pharmaceutical industry took the government to court and the US government threatened trade sanctions. Among other things, the TRIPS Agreement was invoked, both in the media and in the Pharmaceutical Manufacturers Association court documents, in an attempt to stave off these measures. It should be noted that the measures complained of are ones that exist in numerous other countries and should be permissible under TRIPS. Canada, for example, has a Patented Medicines Prices Review Board with the mandate to prevent "excessive" pricing of patented pharmaceuticals. Similarly, South Africa's legislation proposed to establish a pricing committee to establish a transparent price control mechanism. As a result of the legal proceedings and the US threats of trade sanctions, implementation of the legislation has been delayed for 4 years, during which time millions more have become infected with HIV or died of AIDS.

Brazil has also faced the use of the TRIPS Agreement and the WTO complaint mechanism in efforts to block its pursuit of policies making medicines affordable. Brazil has been lauded as a developing country with an effective treatment strategy that provides anti-retroviral drug coverage free of charge to some 90,000 people living with HIV/AIDS, drastically reducing its mortality rate and the costs associated with hospitalisations of sick people. One reason for its success has been the development of a strong capacity to manufacture generic drugs, meaning it has been able to produce some drugs generically before patent protection for pharmaceuticals was introduced as a result of TRIPS, and it has been in a strong position to bargain for price reductions with proprietary pharmaceutical companies. As a result, it was targeted for a WTO complaint by the US, which alleged that Brazil was in breach of its TRIPS obligations for enacting legislation allowing a compulsory licence to be issued on a patented product if, after 3 years of patent protection, the patent-holder was not manufacturing the product in Brazil. After widespread criticism of the US government, the dispute has now been (temporarily) settled. But the incident is yet another example of how the TRIPS Agreement and the WTO dispute settlement machinery can be invoked in attempts to block measures that promote the public interest in access to affordable medicines.

These examples demonstrate the need for unambiguous direction at the highest levels of the WTO that the TRIPS Agreement does in fact contain the flexibility that some (including Canada) have claimed it has. A Ministerial Declaration is the best, clearest way to ensure that public health and human rights are not sacrificed in the interpretation of this treaty.

4. Will Canada take action?

At a recent WTO/WHO workshop in April 2001, the Director-General of the World Health Organisation reiterated this key point: " We have heard quite clearly that the price of drugs matters - it matters to poor people, and it matters to poor countries… The TRIPS Agreement contains public health safeguards… Countries' rights to exercise these safeguards must be respected."[13]

Indeed, Minister Pettigrew 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."[14] Minister Pettigrew even warned partners against the risks of holding trade talks that would not significantly address the needs the needs of developing countries.[15]

Such statements are certainly true in the case of ensuring access to vital medicines. Canada has an obligation to ensure that the TRIPS Agreement and other international treaties assist, rather than hinder, developing countries in this task. Failing to support such efforts means Canada will confirm that claims about the shared benefits of globalization are mere rhetoric, with the benefits reaped principally by the corporate interests of the global North at the expense of the health and lives of people in the global South.

Today, there is a dire imbalance between the sanctity of patents and the health of people. Access to essential medicines should not be a luxury reserved for the wealthy, but should be promoted as a critical component of the human right to health, and as a means to meet global commitments to eradicate poverty. 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 most profitable industry) will have little impact on overall company profits, but will protect the dignity and human rights of millions of poor people.

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[13] Dr. Gro Harlem Brundtland, Director General, World Health Organization. Closing remarks at the WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, Hösbjor, Norway, April 2001.

[14] Hon. Pierre Pettigrew. "How trade will save the world." *The Globe & Mail*, 11 October 2001: A19.

[15] Minister Pierre Pettigrew expressed himself very clearly: "[O]ne of the biggest challenges in my view is to ensure that the concerns of smaller economies are addressed in a meaningful fashion. (…) These smaller nations do not have all the advantages that people in richer nations take for granted. We enjoy diversified economies; prosperous, **healthy**, well-educated populations; long traditions of democracy and the rule of law; clean environments; **solid infrastructures**. They want these things too, but they face many obstacles, some environmental, some historical, some **structural**. Larger economies are better able to absorb the shocks that come with globalization. (…) Many less-developed countries are therefore **understandably wary** about entering into an agreement that could overwhelm their fragile economies. We must not let that happen. **Trade liberalization must benefit all economies, particularly the smaller ones. That is another lesson from Seattle. At that meeting, less-developed countries made their voices heard, demanding that future trade talks take into account their concerns**": "Notes for an address by the Honourable Pierre Pettigrew, Minister for International Trade, to the European Policy Centre – THE ROAD TO DOHA: LESSONS FROM THE FTAA", Brussels, Belgium, 18 May 2001.

Countries must be allowed to balance exclusive patent rights with public interest concerns, including making medicines affordable to treat serious diseases. They should not face the threat of unilateral trade sanctions, nor complaint procedures at the WTO invoking the TRIPS Agreement, for acting to safeguard the health and human rights of their people. But to date, this flexibility has not been realised in dispute settlement decisions or in the practice of some WTO member countries. A clear Ministerial Declaration is required.

[Ends]

ANNEX 1:

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**.**

ANNEX 2:

PROPOSAL FROM A GROUP OF DEVELOPED COUNTRIES

PART I -- PROPOSAL FOR PREAMBULAR LANGUAGE FOR MINISTERIAL DECLARATION

IP/C/W/313
4 October 2001
(01-4779)

Council for Trade-Related Aspects of Intellectual Property Rights

Preambular language for ministerial declaration

Contribution from Australia, Canada, Japan, Switzerland and the United States

During the special discussion of the TRIPS Council on 19 September 2001, the delegations of Australia, Canada, Japan, Switzerland and the United States communicated the following text to the Secretariat and have requested it to be circulated as a TRIPS Council document.

Access to medicines for HIV/AIDS and other pandemics

We Members of the WTO, recognize that access to medicines for treatment of HIV/AIDS and other pandemics, such as malaria and tuberculosis, especially by the poorest populations of the globe, is one of the major challenges for the global community and for its sustainable development;

recognize that an effective response to this challenge requires a mix of complementary social, economic, health policies and practices, including education and prevention programmes;

recognize that it is, therefore, the common responsibility of international organisations, governments, non-governmental organisations and private actors, through their areas of responsibility, to contribute to the promotion of the most favourable conditions for improving access to medicines for treatment of HIV/AIDS and other pandemics;

recognize that among the determinant factors for improving access to medicines are efficient infrastructure to distribute, deliver and monitor drug usage and provide necessary information and education; increased research and development particularly targeted at the major communicable diseases of relevance for developing countries; mechanisms to finance drug purchases, and affordable pharmaceuticals; and the implementation of effective and sustainable healthcare systems;

recognize that strong, effective and balanced protection for intellectual property is a necessary incentive for research and development of life-saving drugs and, therefore, recognize that intellectual property contributes to public health objectives globally.

Therefore, we Members of the WTO reaffirm that the TRIPS Agreement contributes to the availability of medicines and reaffirm our commitment to the TRIPS Agreement and its implementation;

reaffirm the appropriateness of Members using the flexibility afforded by the Agreement to ensure that medicines for treatment of HIV/AIDS and other pandemics are available to their citizens who need them, particularly those who are unable to afford basic medical care;

take note of discussions held by the Council for TRIPS that have clarified Member's views of the flexibility provided under the Agreement;

encourage Members, whatever the exhaustion regime that they may have chosen, to take measures to prevent pharmaceuticals provided to the poorest populations of the globe under discounted pricing schemes or supplied under aid-schemes from being diverted from those for whom they were destined to markets for which they were not intended;

pledge, in the context of the new global fund, to work with the private sector and with affected countries to facilitate the broadest possible provision of drugs in an affordable, medically effective, and WTO-consistent manner; and

reaffirm the importance for developing and least-developed country Members of technical assistance for implementing their obligations under the TRIPS Agreement, while taking into account health concerns.

Clarification language
(To be provided.)

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PART II -- PARTIAL PROPOSAL FOR OPERATIVE PROVISIONS OF A MINISTERIAL DECLARATION

Non Paper
(Proposal presented 21 September 2001 at the Council for TRIPS)

Contribution from Canada, the Czech Republic, Japan, New Zealand, Switzerland and the United States.

This document is submitted without prejudice to these Members' ability to work together to develop additional clarifications.

Regarding Access to medicines for HIV/AIDS and other Pandemics

MINISTERS declare that

1. Each provision of the TRIPS Agreement should be read in accordance with the customary rules of interpretation of public international law as reflected in the Vienna Convention on the Law of Treaties;

2. Article 31 of the TRIPS Agreement, which prescribes the provisions under which Members can grant compulsory licenses, leaves WTO Members the freedom to determine the grounds for granting compulsory licenses, so long as the provisions set out in the Agreement are respected, including that which specifies that each compulsory licence must be considered on its individual merits;

3. An affected Member’s government can declare pandemics of life-threatening communicable diseases such as HIV/AIDS, malaria and tuberculosis, as situations of ‘national emergency’ or as a ‘circumstance of extreme urgency’ within the meaning of Article 31(b) of the TRIPS Agreement;

4. Although the TRIPS Article 28.1 provides exclusive importation right for patented products, Article 6 provides that dispute settlement is not available to challenge a Member’s practices concerning the

exhaustion of rights, so long as those practices comply with Article 3 and 4; therefore, the TRIPS Agreement does not prevent Members from adopting the
exhaustion regime that they regard as in their best interests;

5. Without prejudice to the exhaustion regime a Member has chosen, intellectual property rights are exhausted in a market when the goods to which these intellectual property rights apply have been put on that market by the right holder or with his/her consent;

6. Whatever the exhaustion regime they may have chosen, Members are encouraged to take measures to prevent pharmaceuticals provided to the poorest populations of the globe under discounted pricing schemes or supplied under aid-schemes from being diverted from those for whom they were destined to markets for which they were not intended;

7. …

[ends]