Global Access to Medicines: Will Canada Meet the Challenge?

A Submission to the Standing Committee on Industry, Science and Technology

regarding

Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act

Canadian HIV/AIDS Legal Network

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"Lack of access to antiretroviral therapy (ART) is a global health emergency… To deliver antiretroviral treatment to the millions who need it, we must change the way we think and change the way we act."

- Dr. LEE Jong-wook, Director-General, World Health Organization, 1 December 2003 (World AIDS Day)

"People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off."

- Kofi Annan, UN Secretary-General, 26 April 2001

"We are using generic medicines from India in the [MSF] program in Malawi, which keeps the price as low as possible. The less expensive the drugs, the less expensive the program, and the more people can be treated. … I would like to ask those people who say we should only do [HIV] prevention: If this epidemic were claiming so many lives in your community, would you really accept letting all of us already living with HIV die?"

- Fred Minandi, person living with HIV/AIDS from Malawi, 2002 International AIDS Conference

I consider myself to be very lucky. I have access to antiretroviral medication when hundreds of others don't. Many people I know have died because they did not have access to these pills. We urgently need ARV for the people who need it most. There are many people who don't know from one month to the next if they will still be able to afford the medication that allows them to continue living. There are others who don't even have the tablets temporarily. This is terrible.

- Rosa Gonzalez, person living with HIV/AIDS from Honduras, December 2003

BACKGROUND: WTO PATENT RULES AND CANADA'S BILL C-9

The WTO TRIPS Agreement and the Doha Declaration

On 14 November 2001, at the WTO's Fourth Ministerial Conference in Doha, Qatar, member countries unanimously adopted a ministerial Declaration on the TRIPS Agreement and Public Health.[1] The "Doha Declaration", as it came to be known, was made in response to criticisms from numerous developing countries and from civil society organizations to the effect that WTO rules on intellectual property – and especially the rules on pharmaceutical patents – were impeding access to more affordable medicines. This is a matter of particular concern in developing countries that are facing HIV/AIDS and other health problems and that are also burdened by widespread poverty, with few resources to spend on expensive patented drugs.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires all WTO countries to adopt certain minimum standards for protecting private intellectual property rights, including with respect to pharmaceutical inventions. Those rules create temporary monopolies over patented pharmaceuticals, meaning the company holding the patent can charge high(er) prices.

The implications for developing countries needing more affordable medicines are obvious. Indeed, the consequences are deadly, whether for people suffering from diseases or health conditions that have long plagued the world's poor or in the face of recent and growing global crises such as the HIV/AIDS pandemic.

At a recent address, Nobel laureate Dr. Joseph Stiglitz, former Chief Economist at the World Bank and Chairman of the Council of Economic Advisors to the US President, commented on the WTO's TRIPS Agreement and stressed the need for a better balance between users and producers of intellectual innovation. Stiglitz noted, in particular, that when developing countries signed on to the TRIPS Agreement in 1995 – which step they took reluctantly under considerable pressure from the US, the European Union and other wealthy countries such as Japan and Canada – they were essentially "signing a death warrant."[2] His remarks are an apt characterization, given the death toll ravaging the developing world as a result of HIV/AIDS, tuberculosis, malaria and myriad other conditions, as well as the ongoing lack of access to affordable medicines, described recently by the Director-General of the World Health Organization as a "global emergency".

Despite the gravity of this situation, developing countries continue to face considerable pressure to refrain from using the "flexibilities" contained in the TRIPS Agreement that allow WTO Members to set their own balance between protecting private patent rights and pursuing important public policy objectives such as protecting public health. Developed countries have exerted this pressure notwithstanding their own steps to limit patent rights in the interests of health. The most notable recent

[1] WT/MIN(01)/DEC/2.

[2] Dr. J. Stiglitz, ""The Process of European Integration and the Future of Europe", 2004 Gunnar Myrdal Lecture to the UN Economic Commission for Europe (UNECE), Geneva, 11 February 2004, reported at: "Stiglitz cautions against rigid economic development model", BRIDGES Weekly Trade News Digest, Vol. 8, No. 6, 19 February 2004 (Geneva: International Centre for Trade & Sustainable Development), available at: http://www.ictsd.org/weekly/index.htm.

example can be seen in the actions of the US and Canadian governments in October 2001 when, concerned about the possible use of anthrax as a form of bioterrorism, these governments faced the possibility of having to purchase, on short notice, large quantities of the antibiotic drug ciprofloxacin at the high price demanded by the patent-holder. The US and Canadian governments showed that, when it came to the health of their own people, they were willing to limit patent rights in the public interest.

The pressure on developing countries has also continued notwithstanding that the TRIPS Agreement itself recognizes that countries need to balance competing objectives, with express reference to public health considerations. Note, for example, that **Articles 7 and 8 of the TRIPS Agreement** set out, respectively, the "Objectives" and the "Principles" that must guide the treaty's interpretation and implementation.

WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Article 7 – Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 – Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Given this ongoing pressure to prevent developing countries from pursuing the public interest through measures such as compulsory licensing, developing countries pushed for the Declaration on the TRIPS Agreement and Public Health that was ultimately adopted unanimously by WTO Members in November 2001, at the 4th Ministerial Conference of the WTO. The Declaration reaffirmed countries' right to use the flexibility in the TRIPS Agreement to protect public health and to improve access to affordable medicines, including through compulsory licensing of pharmaceutical patents. (See excerpts from the Doha Declaration below.)

Excerpts from the Declaration on the TRIPS Agreement and Public Health (Doha, November 2001)

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. […]

4. 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.

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.

5. Accordingly, and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

c. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

6. We recognize that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

The Doha Declaration is an international document with binding legal effect on WTO Members. As a matter of law, it must guide the interpretation and implementation of the TRIPS Agreement. Under the 1969 *Vienna Convention on the Law of Treaties*, any interpretation of the TRIPS Agreement, which is a treaty between all WTO Members, must take into account the Doha Declaration as either a "subsequent agreement" between WTO Members regarding the interpretation of TRIPS or the application of its provisions, or as a

"subsequent practice" in the application of TRIPS that establishes WTO Members' agreement regarding its interpretation, or both.[3]

Under WTO law, these *Vienna Convention* rules for interpreting treaties have been recognized as rules of customary international law, meaning they bind all WTO countries, not just those that have also ratified the *Vienna Convention*. Furthermore, the Doha Declaration itself (para. 5(a)) also expressly reaffirms that the TRIPS Agreement should be interpreted in accordance with these rules of customary international law and in light of the Agreement's stated objectives and principles (ie, Articles 7 and 8 noted above).

This means that the Doha Declaration must guide how Canada interprets and implements the TRIPS Agreement, including any subsequent texts that are adopted by WTO Members that modify the Agreement – such as the WTO General Council Decision of 30 August 2003, which is the basis for Canada's Bill C-9.

The WTO General Council Decision of 30 August 2003: Genesis of Bill C-9

The Doha Declaration did not solve all the problems facing developing countries, however. As noted in the box above, WTO Members also recognized in the Doha Declaration (paragraph 6), 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 is because a country that lacks its own capacity to make pharmaceuticals is not able to effectively give compulsory licences to domestic producers to make those products locally. Most developing countries lack sufficient capacity to manufacture the pharmaceuticals they need.

However, compulsory licences could still be used to authorize imports of generic pharmaceuticals made elsewhere. But, under Article 31(f) of the TRIPS Agreement, countries that have the capacity to make generic pharmaceuticals – and could therefore be potential exporters – are usually restricted to using compulsory licensing "predominantly" for supplying their own domestic market. This limits the possibility of generic pharmaceutical makers in one country (e.g., Canada) getting compulsory licences authorizing them to produce cheaper products for export to other countries in need

Having recognized this problem, WTO members committed to finding "an expeditious solution" by the end of 2002. Unfortunately, they were unable to meet this deadline, and it was not until August 2003 that a solution was agreed.

Between November 2001 and August 2003, WTO Members negotiated over the text of a solution to this problem. Over the course of those negotiations, some developed countries tried to impose conditions and restrictions on any "solution", such as:

- limiting which countries would be able to use the solution; and
- creating a limited list of diseases for which compulsory licensing could be used to import cheaper generic pharmaceuticals.

[3] *Vienna Convention on the Law of Treaties*, Article 31(3).

In particular, the US and a handful of developed countries pushed restrictive proposals that were at odds with the very letter and spirit of the Doha Declaration, which had just been unanimously adopted and which had mandated WTO Members to overcome the difficulty faced by many countries in making "effective use" of compulsory licensing.

In December 2002, a decision that had been accepted by every other WTO Member was rejected by the US because it wanted to further weaken and narrow the "solution". Eight months later, in August 2003, the US finally agreed to the text that had been previously accepted by all other countries in December 2002. During those eight months, the US and some other developed countries made further efforts to restrict the scope of the "solution" – and more than 1.5 million people had died of AIDS, most of them in the developing world and most because they could not afford to buy the medicines that could have saved or prolonged their lives.

The efforts to limit the "solution" by attaching a limited list of diseases were firmly rejected as ethically unacceptable and illogical from a public health perspective. The US did succeed in convincing or pressuring a handful of countries into formally stating they would not use the solution to issue compulsory licences to import cheaper generic pharmaceuticals.

Finally, on 30 August 2003, a consensus was reached by all WTO Members on the text of a solution that relaxes the restriction in TRIPS Article 31(f) on using compulsory licensing to authorize the production of generic pharmaceuticals for export in any significant quantity. That consensus took the form of a Decision by the WTO's General Council.

Bill C-9 is Canada's legislation to implement the WTO General Council Decision of 30 August 2003. The bill should, therefore, fully reflect the flexibility that the WTO Decision creates for countries to use compulsory licensing to import cheaper, generic pharmaceutical products.

THE HUMAN RIGHT TO HEALTH: CANADA'S INTERNATIONAL OBLIGATIONS TO PROMOTE ACCESS TO MEDICINES

Canada's implementation of the WTO Decision of 30 August 2003 must also respect, and be informed by, our other international obligations – and in particular, our obligations under international human rights law.

Since the adoption by treaty of the **Constitution of the World Health Organization** (WHO) in 1945, the international community has recognized that the "enjoyment of the highest attainable standard of health" is a "fundamental right".[4] As a Member State of the World Health Assembly, the supreme decision-making body for the WHO, Canada is a signatory to this treaty and recognizes the right to health as a fundamental right.

As a member of the United Nations, Canada is legally bound by the obligations in the **UN *Charter*** to work towards achieving "solutions of international…health…problems" and achieving the universal realization of "human rights" for all.[5] The ***Universal Declaration of Human Rights***, the most universally accepted articulation of the human rights obligations referenced in the UN Charter, and a document which Canada has reaffirmed on countless occasions, declares that:

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including…medical care. (Article 25)
>
> Everyone has the right to share in scientific advancement and its benefits. (Article 27)

More recently, in the 1993 ***Vienna Declaration***, Canada joined 171 other UN Member States in unambiguously declaring that: "Human rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of governments."[6]

Furthermore, Canada has ratified, and is legally bound by, the ***International Covenant on Economic, Social and Cultural Rights*** (ICESCR), which provides that:

> The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the States Parties … to achieve the full realization of this right shall include those necessary for …the prevention, treatment and control of epidemic diseases. (Article 12)

It is well recognized that rights such as the right to health cannot be fully realized overnight. But there is a binding legal obligation for all states that have ratified the ICESCR to take positive steps toward eventually achieving these fundamental human rights. This has been recently reiterated, specifically in

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[4] Constitution of the World Health Organization, 14 U.N.T.S. 185.

[5] *Charter of the United Nations*, T.S. 67 (1946), Articles 55 and 56.

[6] *Vienna Declaration and Programme of Action*, adopted by 171 states (including Canada) at the UN World Conference on Human Rights, Vienna, 1993 [emphasis added].

the health context, by the UN Committee on Economic, Social and Cultural Rights, the international body of independent experts appointed by UN Member States to monitor the implementation by States of their obligations under the ICESCR. In its recent **General Comment 14 on the right to health**, the Committee reminded States which are parties to the ICESCR that they "have a specific and continuing obligation to move as expeditiously as possible toward the full realization" of the right to health set out in Article 12, and this includes adopting "appropriate legislative… and other measures" toward this end.[7] The Committee has also reminded States that its obligations are international in scope, and they are required to "take steps, individually and through international assistance and cooperation… towards the full realization of the rights recognized in the Covenant, such as the right to health."[8]

Canada has also committed itself to contributing to the global response to the global HIV/AIDS crisis. At the UN General Assembly's Special Session on HIV/AIDS in June 2001, UN Member States unanimously adopted a ***Declaration of Commitment on HIV/AIDS***, in which they promised, among other things, to:

> By 2003… in an urgent manner make every effort to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections, and effective use of quality-controlled anti-retroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance… (para. 55)

Canada has also supported several **unanimous resolutions of the UN Commission on Human Rights** in which the Commission has recognized that, in the context of pandemics such as HIV/AIDS, tuberculosis and malaria, "access to medication…is one fundamental element for achieving progressively the full realization of the right of everyone to the highest attainable standard of physical and mental health."[9]

Finally, the Joint UN Programme on HIV/AIDS (UNAIDS) and the Office of the UN High Commissioner for Human Rights have produced ***HIV/AIDS and Human Rights: International Guidelines*** "to assist States in translating international human rights norms into practical observance in the context of HIV/AIDS".[10] Guideline 6, recently revised in September 2002, deals specifically with the issue of "Access to prevention, treatment, care and support". It provides that:[11]

> States should enact legislation to provide for the regulation of HIV-related goods, services and information, so as to ensure widespread availability of quality prevention

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[7] UN Committee on Economic, Social and Cultural Rights. *General Comment 14: The right to the highest attainable standard of health (Art. 12)"*, 4 July 2000, U.N. Doc. E/C.12/2000/4, paragraphs 31 & 33 ["General Comment 14"].

[8] General Comment 14, paragraph 38.

[9] E.g. UN Commission on Human Rights, Resolutions 2001/33, 2002/32, 2003/29.

[10] *HIV/AIDS and Human Rights: International Guidelines* (Geneva & New York: UNAIDS & OHCHR, 1998), paragraph 10.

[11] *HIV/AIDS and Human Rights: International Guidelines - Revised Guideline 6: Access to prevention, treatment, care and support* (New York & Geneva: UNAIDS & OHCHR, September 2002).

measures and services, adequate HIV prevention and care information, and safe and effective medication at an affordable price.

States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV/AIDS prevention, treatment, care and support, including antiretroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV/AIDS and related opportunistic infections and conditions.

States should take such measures at both the domestic and international levels, with particular attention to vulnerable individuals and populations.

"The procedures for implementing the new legislation should facilitate the goal of improving access to drugs and promoting public health in developing countries."

- Mr. Paul Hunt, UN Special Rapporteur on the Right to Health, 7 November 2003, commenting on Bill C-56 [precursor to Bill C-9]

In implementing the WTO General Council Decision of 30 August 2003, the Government of Canada and Members of Parliament should take note of Canada's international human rights obligations as they relate to health. Bill C-9 is Canada's implementation of that WTO Decision. Therefore, in reviewing and enacting Bill C-9, legislators should craft the amendments to the Patent Act in a fashion that fully respects and reflects the obligation to take steps leading toward the full realization of the human right to health, including by promoting access to affordable medicines for all.

COMPULSORY LICENSING: THE CANADIAN EXPERIENCE

Compulsory licensing was first introduced in intellectual property legislation in Britain in 1883, and has formed part of the law and practice of many industrial countries for more than a century, including Australia, Canada, Germany, Ireland, Italy, New Zealand, the United Kingdom and the United States.[12] As the UN Development Programme reports, since the WTO TRIPS Agreement was adopted,

> … compulsory licences have been used in Canada, Japan, the United Kingdom and the United States for products such as pharmaceuticals, computers, tow trucks, software and biotechnology – particularly as antitrust measures to prevent reduced competition and higher prices. In the United States compulsory licensing has been used as a remedy in

[12] UN Development Programme. *Human Development Report 2001: Making New Technologies Work for Human Development*, at 107.

> more than 100 antitrust case settlements, including cases involving antibiotics, synthetic steroids and several basic biotechnology patents.
>
> In contrast, not one compulsory licence has been issued south of the equator. Why? Pressure from Europe and the United States makes many developing countries fear that they will lose foreign direct investment if they legislate for or use compulsory licences. In addition, attempts to use such licences could result in long, expensive litigation against the pharmaceutical industry. But alternative legislative models can be used to avoid the emphasis on litigation and to create provisions suited to the needs of developing countries.[13]

Canada is the developed country with the most extensive experience of using compulsory licensing to balance the public policy objectives of patent protection with patient protection. "The Canadian government has issued more compulsory licences on medicines than any other government. […] From 1969 to 1992, Canada issued more than 600 compulsory licences on medicines. In nearly every case, the compensation to the patent owner was a standard 4 percent royalty applied to the generic competitor's sale price."[14,15]

In the 1980s, a Royal Commission of Inquiry on the Pharmaceutical Industry ("the Eastman Commission") concluded that the practice of compulsory licensing *had not adversely affected* the research-based Canadian pharmaceutical industry and had saved Canadian consumers some $200 million in one year alone (1983).[16] More recently, the UNDP has estimated that in 1991-92, the practice of compulsory licensing saved Canadian consumers an estimated $171 million (US) in drug costs.[17]

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[13] UN Development Programme. *Human Development Report 2001: Making New Technologies Work for Human Development*, at 107.

[14] James Love, *Compensation for Non-voluntary Use of a Patent on Medical Technologies*, 6 September 2003 (on file), with further reference to: F.M. Scherer, "The Economic of Compulsory Drug Patent Licensing", May 2003; Jerome H. Reichman & Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: The Canadian Experience*, UNCTAD/ICTSD Capacity-Building Project on Intellectual Property Rights and Sustainable Development, October 2002; Joel Lexchin, "Pharmceuticals, patents and politics: Canada and Bill C-22", *International Journal of Health Services* 1993; 23: 47-60; and Joel Lexchin, "After compulsory licensing: coming issues in Canadian pharmaceutical policy and politics," *Health Policy* 1997; 40: 69-80.

[15] In some cases, courts upheld lower royalties in the case of compulsory licences on medicines: e.g., see *Beecham Group Ltd. v. Frank W. Horner Ltd.*, [1974] 1 F.C. 9 (Federal Court of Appeal unanimously upholding the Commissioner's decision to award a 1% royalty on the net selling price of the drug ampicillin).

[16] Harry C. Eastman, *Report of the Commission of Inquiry on the Pharmaceutical Industry* (Ottawa: Supply and Services Canada, 1985) ("Eastman Report"). Four other commissions in the 1960s had previously confirmed that patents inhibited competition and led to excessive prices of patented medicines; one of those Commissions declared that "either the industry will make…drugs available at the lowest possible cost, or it will be necessary for…government to do so": Royal Commission on Health Services ("Hall Commission"), Report 40 (1964).

[17] UN Development Programme. *Human Development Report 2001: Making New Technologies Work for Human Development*, at 107.

Canadian approach to royalties for pharmaceutical compulsory licences

Furthermore, Canadian law has, in the past, provided clear guidance as to the public policy of promoting public health goals that should underlie the use of compulsory licensing of pharmaceuticals, and which should therefore also inform the remuneration paid to patent holders in the event of compulsory licensing. Until 1993, Canada's Patent Act stated that:

> (4) Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine, an application is made by any person for a licence…., the Commissioner shall grant to the applicant a licence to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a licence.
>
> (5) In settling the terms of a licence granted under subsection 4… and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.[18]

We have noted above that past Canadian law and practice of compulsory licensing in the pharmaceutical sector included, as a general rule, a royalty rate of 4%. In his first decision under the new provisions introduced in 1969 regarding compulsory licensing of medicines, the Commissioner of Patents deemed a royalty amounting to 4% of the net selling price of the drug in final dosage form to be adequate remuneration for the patent holder.[19] This approach was upheld by the Exchequer Court of Canada,[20] and the Supreme Court of Canada dismissed the patentee's further appeal on the basis that there were no grounds to interfere with the decision of the Exchequer Court that had affirmed the Commissioner's decision.[21,22]

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[18] *Patent Act*, R.S.C. 1985, c. P-4, s. 39(4)-(5), previously ss. 41(4)-(5) in R.S.C. 1970, c. P-4. While amendments in 1987 (Bill C-22) amended certain aspects of the statute relating to compulsory licensing in the case of medicines, this statement of policy regarding the appropriate approach to remuneration for the patent holder in the event of compulsory licensing remained intact. Further amendments in 1993 (Bill C-91) repealed s. 39 of the Patent Act.

[19] *Hoffman-LaRoche* v. *Frank W. Horner Ltd.*, [1970] 61 C.P.R. 243 (Comm'r of Patents).

[20] *Hoffman-LaRoche v. Frank W. Horner Ltd.* (1970), 64 C.P.R. 93 (Ex. Ct.)

[21] *Hoffman-LaRoche Ltd.* v. *Frank W. Horner, Ltd.*, [1972] S.C.J. No. 17 (QL).

[22] Reichman and Hasenzahl have recently completed an exhaustive review of the experience of compulsory licensing in Canada, and note that, on average, royalties awarded in cases of compulsory licences for medicines were lower than licences granted for other products under the "local working" provisions of the Patent Act: " The royalty rates in these cases typically varied according to the facts. Examples include a per piece royalty of 10 cents on watch bracelets; 5 % of cost on a machine and its component parts; between 6 % and 10 % on parts for a machine with a two cent per piece minimum; and 3 ½ % of the net selling price of an article. However, these practices should not be confused with the Commissioner's duties pursuant to applications for compulsory licensing of pharmaceutical and agricultural inventions, where he was governed by guidelines, including a 4% "rule of thumb royalty," that were not contingent on a failure to work…. [O]ne should note that royalties tended

In upholding the Commissioner's approach of setting a 4% royalty, the Exchequer Court also referred to the guidance previously provided by the Supreme Court of Canada in a related case:

> No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary, Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may be "available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention."[23]

This standard royalty rate of 4% was adopted, and upheld in most cases by the courts, in the circumstance where the compulsory licence was issued to authorize sales in the relatively wealthy Canadian market. Therefore, in the case of compulsory licensing of pharmaceuticals for export to developing and least-developed countries, the very purpose of which is to supply more affordable medicines to countries that are poorer than Canada, it would be appropriate that a royalty rate be certainly no higher, and in all likelihood lower, than this figure of 4%. As drafted, Bill C-9 makes reference to a royalty rate of 2%, which figure is appropriate given the countries that are to benefit from this initiative.

The Canadian approach to setting compensation for patent-holders in the event of compulsory licensing has been central to the royalty guidelines recommended to developing countries by the UN Development Programme (UNDP). Those recommendations should also influence Canada's approach in Bill C-9, which implements a scheme whereby compulsory licensing can be effectively used to secure access to more affordable pharmaceuticals in developing countries. In its *2001 Human Development Report*, the UNDP has recommended that developing countries adopt royalty guidelines to provide greater transparency and predictability. Specifically, UNDP recommended that:

> Compensation needs to be predictable and easy to administer; royalty guidelines reduce uncertainty and speed decision. Germany has used rates from 2-10%, while in Canada the government used to pay royalties of 4%. Developing countries could award an extra 1-2% for products of particular therapeutic value and 1-2 % less when research and development has been partly covered by public funds.[24]

When considering Canada's initiative to amend the Patent Act – so as to allow other countries, lacking sufficient manufacturing capacity, to make effective use of compulsory licensing to obtain Canadian-made generic pharmaceuticals – regard should be had to our own experience of using compulsory licensing for the express purpose of improving Canadians' access to more affordable medicines.

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to be higher in cases dealing with the working requirement than in cases of pharmaceutical and agricultural inventions." Jerome Reichman and Catherine Hasenzahl (2002), *supra*, at 9-10.

[23] *Hoffman-LaRoche Ltd.* v. *L.D. Craig Ltd., Bell-Craig Pharmaceuticals Division*, [1966] S.C.R. 313, 56 D.L.R. (2d) 97, 48 C.P.R. 137 at 140.

[24] UN Development Programme. *Human Development Report 2001: Making New Technologies Work for Human Development*, at 108.

Furthermore, it should be kept in mind that, while the former regime allowing regular compulsory licensing of pharmaceutical patents was changed in the late 1980s and early 1990s, Canadian law continues to manifest a concern for containing excessive pricing of medicines. The law also continues to recognize that patent rights may sometimes be limited in light of other important public policy concerns. In particular:

- Canada's *Patent Act* continues to provide the possibility of compulsory licensing, for the purposes of supplying the domestic market, in cases where a patentee abuses their exclusive rights under a patent (ss. 65-71).

- Canada's *Patent Act* continues to include provisions authorizing "government use" of patented inventions (ss. 19-19.3). All that is required in such cases is notification to the patentee by the Commissioner and the payment of "such amount as the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization."

- Under Canada's *Competition Act*, if a patent holder uses its patent rights in a manner that "unduly" prevents or lessens competition, the Federal Court may grant a compulsory licence to use a patented invention "on such terms as it deems appropriate". Alternatively, it may revoke the patent entirely (s. 32).

- Under the Patent Act, Canada aims to contain the prices of patented medicines through the Patented Medicine Prices Review Board (PMPRB), and in recognition of the significant cost savings for public health insurance programmes, Canadian jurisdictions have long pursued politics that promote "generic substitution" where this is feasible.

In amending Bill C-9, Canada should not forget our own use of compulsory licensing

Canada has already agreed, in the November 2001 Doha Declaration and the WTO Decision of 30 August 2003, that countries lacking insufficient pharmaceutical manufacturing capacity should be able to "make effective use" of compulsory licensing to obtain more affordable pharmaceutical products. In light of Canada's own history and current practice, it would be an unacceptable double-standard and an act of bad faith for Canada to implement the WTO Decision of 30 August 2003 in a fashion that falls short of fully respecting developing countries' clear legal right to effectively use compulsory licensing to address health problems on the grounds they determine.

KEY AREAS OF CONCERN WITH BILL C-9

In this section, we identify five areas of concern with Bill C-9 and explain why these are concerns. In Appendix I, we provide a detailed list of recommended amendments to Bill C-9, including our recommendations for addressing these key areas of concern. The five areas of concern are:

1. the **"right of refusal" provisions** (in sections 21.04(6) and (7));

2. the existence of a **limited list of pharmaceutical products** (Schedule 1);

3. the **exclusion of non-WTO developing countries** (Schedule 3);

4. the failure to recognize the possibility of **non-governmental and international organizations contracting directly with generic producers** for needed pharmaceutical products (section 21.04(2)(f);

5. the **potential for the regulatory system to be too inflexible**, with the consequence of hindering the manufacture and export of some of the most needed pharmaceutical products.

We discuss each of these concerns in detail in this brief, and incorporate our suggested amendments into the detailed table found in Appendix I.

1. The "right of refusal": a fatal flaw in Bill C-9

> "That is a very serious flaw in the bill, and it has to come out; it is important that it comes out, because it does compromise the integrity of the legislation."
> *- Stephen Lewis, UN Secretary-General's Special Envoy on HIV/AIDS in Africa, regarding the "right of refusal", The Globe & Mail, 14 Feb 2004*

"Right of refusal" will render Bill C-9 ineffective by blocking competition

Subsections 21.04(6)(a) and (7)(a) create a "right of refusal" for the patent holder, in the form of a "right" to scoop contracts that generic producers have negotiated to supply products at lower prices to purchasers in developing countries. These subsections say that, within 30 days of having received notice that a generic producer intends to apply for a compulsory licence, a patent holder may notify the Commissioner of Patents that it will supply the product on the terms of the contract that the generic producer has negotiated with a purchaser. Recall that, under s. 21.04(2)(f), a generic producer must file with the Commissioner, along with its notice that it intends to seek a compulsory licence, the terms and conditions of the contract that is the basis for its application, and that the Commissioner must provide this information to the patent holder.

If the patent holder exercises this "right" provided for in either s. 21.04(6)(a) or (7)(a), then s. 21.05(5) as proposed by Bill C-9 says that the Commissioner is prevented from issuing a licence to the generic producer.

These provisions represent the most fundamental flaws in Bill C-9. It may be that, in a handful of initial cases in which Canadian generic manufacturers seek compulsory licences to fulfil contracts with developing country purchasers, the developing country will end up receiving a needed pharmaceutical product at a lower price – because the Canadian patent-holding company exercises its "right of refusal" and steps in and supplies the product in accordance with the terms of the contract negotiated between the purchaser and the Canadian generic manufacturer.

Statement of the WHO during negotiations leading to adoption of WTO Decision of 30 August 2003:

"[T]he basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product.

- Statement of the World Health Organization to the WTO Council for TRIPS, 17 September 2002

But such provision obviously remove any incentive for a generic producer to even negotiate such contracts in the first place, since it is blocked from getting the licence it needs to fulfil that contract and it loses the contract itself. Very quickly, as this occurs, Canadian generic manufacturers will have little reason to conclude contracts with developing country purchasers, since they face the certainty or very real possibility of being blocked from obtaining the Canadian licences they need to follow through and, indeed, lose the contracts themselves. Canada's generic pharmaceutical manufacturing capacity will not be effectively available to respond to the world's growing need for lower-cost products, hindering efforts to improve access to needed medicines and other pharmaceutical products.

The problem is further compounded by **section 21.09**, which ordinarily provides that a compulsory licence may be issued for only 2 years. After that period, the generic manufacturer must begin the whole process anew. This provides a further disincentive to use the system envisioned by Bill C-9: there is even less incentive to negotiate contracts to supply countries with generic products if the maximum term of the contract is only 2 years (assuming it is not "scooped" the first time by the patent holder), after which a patent holder will get another opportunity to step in and block the necessary licence from issuing.

In very short order, therefore, Bill C-9 will amount to very little, if the "right of refusal" provisions remain in the bill, frustrating the very objective of improving access to more affordable medicines. These provisions must be deleted in their entirety or the system will become a globally embarrassing example of how <u>not</u> to implement the WTO Decision of 30 August 2003 to assist countries in making effective use of compulsory licensing to obtain more affordable medicines.

"Right of refusal" makes Bill C-9 a "TRIPS-plus" law
This provision has been inaccurately characterized as a "right of first refusal" for patent holders. But, the provision actually amounts to an unnecessary **third** "right of refusal" for patent holders. How so?

▷ Two previous opportunities for patentee to respond to need for lower-cost medicines
It should be remembered that a patent holder already has the opportunity, at any time, to provide its brand-name product at a lower price to a country needing said lower price to address health problems within its population. It is in those circumstances where the patent holder refuses to negotiate a sufficiently affordable lower price that recourse may be had to a compulsory licence to secure the product at a more affordable price. By virtue of being, at least originally, the only seller, the patent holder automatically gets this *first opportunity* to supply would-be purchasers.

If the patent holder chooses not to supply the product itself, at a lower price, and a country wishes to use compulsory licensing to authorize another manufacturer to make the product, TRIPS requires that, in the ordinary course of events, the patent holder be granted another, *second opportunity*. Under TRIPS Article 31(b), before a compulsory licence may be issued, there generally must first be "efforts" made "to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." In other words, before a compulsory licence can be issued, the patent holder first gets to decide whether it will agree to voluntarily grant a licence to the generic producer on "reasonable commercial terms and conditions", such as a royalty payment.[25]

This second opportunity to profit from patent rights is already reflected in ss. 21.04(6)(b) and 21.04(7)(b) of Bill C-9. Under those subsections, the holder of the Canadian patent is given an opportunity to decide, within 30 days of being notified that a generic manufacturer intends to apply for a compulsory licence, whether it will agree to grant a licence to the generic manufacturer in exchange for a royalty, set by s. 21.08 of Bill C-9, at 2% of the value of the pharmaceutical products to be exported under the licence. Canada is entitled to define this 2% royalty as constituting the "reasonable commercial terms and conditions" required by TRIPS Article 31(b).

▷ Bill C-9's third right of refusal for the patentee
But subsections 21.04(6)(a) and 7(a) would create an additional entitlement for the patent-holder – in essence, a *third opportunity* to supply the requested pharmaceutical product. The "right" that is granted by Bill C-9 to the patent-holder is the right to take away the contract negotiated by the generic producer with a developing country purchaser, which also completely blocks the generic producer from obtaining any licence at all.

This sort of provision is not required under Article 31 of the WTO's TRIPS Agreement or any other WTO legal text. It is a "TRIPS-plus" provision in Bill C-9 which undermines the ability of countries to "make effective use of compulsory licensing". This runs counter to the letter and spirit of the Doha Declaration, and amounts to bad faith in the implementation of the WTO Decision of 30

[25] In cases of "national emergency or in other circumstances of extreme urgency", or in cases of "public non-commercial use", this requirement to make efforts to obtain voluntary licence may be waived: TRIPS Article 31(b). Similarly, the requirement may also be waived in the case where a compulsory licence is being issued "to remedy a practice determined after judicial or administrative process to be anti-competitive": TRIPS Article 31(k).

August 2003, the very purpose of which is to create a system by which countries can make effective use of compulsory licensing to import cheaper pharmaceutical products.

The simple table below illustrates the ordinary process for compulsory licensing provided for in the TRIPS Agreement, and compares it with the process that would be established by Bill C-9 if the "right of refusal" provisions remain. The table illustrates that under the TRIPS rules, a generic producer can obtain a licence at the end of the day, either one voluntarily granted by the patent holder or a compulsory one issued by the competent authority. In contrast, under Bill C-9, the generic producer can be completely blocked from obtaining a licence. This "TRIPS-plus" approach to implementing the WTO Decision of 30 August 2003 will be seen by developing countries, quite rightly, as a display of bad faith by Canada after having adopted both the Doha Declaration and the 30 August 2003 decision.

TRIPS Article 31	**"TRIPS-plus": Bill C-9**
<u>Request licence from patent holder:</u>	<u>File notice of intent to apply for licence:</u>
If YES, patent holder agrees "within reasonable period of time", to grant *voluntary licence* on "reasonable commercial terms and conditions".	Within 30 days, patent holder may *EITHER* agree to grant *voluntary licence* in exchange for 2% royalty within 30 days;
➢ Outcome: Generic producer has licence and compensates patent holder as agreed.	➢ Outcome: Generic producer has licence and compensates patent holder as agreed.
If NO, competent authority may issue a *compulsory licence*, and fix the "adequate remuneration" to be paid to the patent holder.	*OR* exercise "right of refusal" to take contract negotiated by generic producer.
➢ Outcome: Generic producer has licence and compensates patent holder as ordered by competent authority.	➢ Outcome: Commissioner of Patents is blocked from issuing compulsory licence to generic producer to fulfil contract.
In the end, the generic producer obtains a licence and may make the product.	*In the end, the generic producer may be prevented from obtaining a licence and lose the contract which it sought to fill.*

Conclusion regarding the "right of refusal" proposed in Bill C-9

The TRIPS Agreement itself expressly provides, in Article 31, for WTO Members to make use of compulsory licensing. But it does not require Canada to grant any "right" to a patent-holder like the "right of refusal" in Bill C-9 in cases where a compulsory licence is sought.

Recall as well that **TRIPS Article 8** expressly says that WTO Members may need to take "appropriate measures… to prevent the abuse of intellectual property rights by right holders or the resort to

practices which unreasonably restrain trade or adversely affect the international transfer of technology." The kind of "right of refusal" provision that is currently contemplated in Bill C-9 runs directly contrary to the spirit of this provision in the TRIPS Agreement: it encourages patent holders to resort to a practice which "unreasonably restrains trade" and will "adversely affect the international transfer" of pharmaceutical technologies to countries trying to import Canadian-made generics.

We conclude that the "right of refusal" found in Bill C-9 is not only "TRIPS-plus" in the sense of providing greater entitlements for patent holders than is required under the TRIPS Agreement, but in fact runs contrary to the very principles that are supposed to underlie the Agreement's interpretation and implementation. By incorporating such a provision in its Patent Act, Canada would be demonstrating not only bad faith in the implementation of the WTO Decision of 30 August 2003, but would be undermining the very principles that have been articulated in the Agreement.

2. Limited list of pharmaceutical products: why is Canada's Cabinet the gatekeeper for developing countries' access to medicines?

Schedule 1 of Bill C-9 sets out a list of patented products for which generic manufacturers may get licences to produce and export. **Section 21.03(1)(a)** says that an order of the federal Cabinet is required to add products to the list.

No need for a list: delete Schedule 1

But there should not be any limited list of pharmaceutical products covered by Bill C-9, nor should a Cabinet decision be required to add to such a list any new pharmaceutical products needed by patients in developing countries.

Developing countries, as sovereign decision-makers, can determine for themselves the pharmaceutical products they need to protect public health in their context. The law of an importing country determines whether it is permitted to import a generic medicine into that country.

WHO Statement on the WTO Decision of 30 August 2003:

"The agreement covers all medicines. Among the diseases that could be more effectively tackled as a result of this decision are AIDS, tuberculosis and malaria.

For the agreement to have the intended impact on public health, countries will need to review the full range of medicines required from multiple suppliers, including generic producers when making purchasing decisions.

- *Statement of the World Health Organization on WTO access to medicines decision, 1 September 2003*

There is no reason why Canada's federal Cabinet should second-guess these decisions. Indeed, such provisions create opportunities for political interference aimed at delaying licences for generic producers. This kind of red tape in Bill C-9 hinders Canadian generic pharmaceutical producers from responding to the needs of developing countries.

Neither TRIPS nor the WTO's August 2003 decision requires any limited list of products. The August 2003 decision simply refers to "pharmaceutical products", which term it defines by referring back to paragraph 1 of the Doha Declaration, which simply refers to "public health problems". Furthermore, the Doha Declaration expressly reaffirms countries' right to determine the grounds upon which compulsory licences may be granted.

During the negotiations leading up to the WTO Decision of 30 August 2003, efforts were made by some countries to limit the products that could be covered. Those proposals were rejected by developing countries, and did not form part of the final text adopted by consensus on 30 August 2003. As South Africa argued, in a late 2002 submission that was supported by numerous other developing countries:

> Paragraph 1 of the [Doha] Declaration does not in any manner qualify "public health" in paragraph 4; neither does it limit the scope of diseases that may be addressed when finding an expeditious solution to the problem referred to in paragraph 6. There must therefore be no *a priori* exclusions regarding diseases that may be addressed by importing and exporting Members or the products in the pharmaceutical sector used to address public health. It is neither practicable nor desirable to predict the pharmaceutical product needs of Members desiring to protect the public health by promoting access to medicines for all.[26]

Schedule 1: Problems with the content of the list

A quick review of the existing Schedule 1 shows that it is already seriously flawed. To take just the example of HIV/AIDS, there are numerous anti-retroviral drugs already on the Canadian market that are missing from the list. These include:

- amprenavir	- nevirapine	- delavirdine
- abacavir	- tenofovir	- didanosine
- lamivudine	- zalcitabine	

- and the two fixed-dose combinations Combivir® (lamivudine + zidovudine) and Trizivir® (lamivudine + zidovudine + abacavir).

Beyond the issue of whether certain specific pharmaceutical products are missing, there is the larger question of how such a list could be created – trying to answer this question reveals the inappropriateness of trying to prescribe any such list at all.

For example, it has been suggested that the products listed by name on Schedule 1, and therefore subject to compulsory licensing for export, should be exclusively or principally those products which appear on the WHO's Model List of Essential Medicines. However, this approach is undesirable and should be rejected, for a number of reasons.

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[26] Cited in: Prof. Fred Abbott, "Canada and the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", Public address at seminar hosted by the North-South Institute, Parliament Hill, Ottawa, 21 October 2003, available at http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/Implement-Paragraph6-Waiver.ppt.

First, the WHO Model List is precisely that – a "model" list, intended for use by countries in devising, in their own contexts and with particular attention to their own needs, their own *national* lists of essential medicines. Second, the name of the WHO Model List is a misnomer – the phrase "essential medicines" suggests that the products on the WHO list are those that are "medically necessary", but clearly a model list cannot be comprehensive in addressing all health needs. In the WHO's own words:

> Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.[27]

Third, it is inappropriate to use the WHO Model List as a "gatekeeper" in Canada's patent law to determine which pharmaceutical products can be made in Canada under compulsory licence and exported to respond to the public health problems identified by importing countries. The WHO Model List was not created with such a purpose in mind. Furthermore, as stated by the WHO in the definition above, "cost-effectiveness" is one of the criteria considered in determining whether a medicine is placed on the WHO Model List – the assessment looks at more than just clinical effectiveness and therapeutic necessity or benefit. High(er) cost of a medicine, therefore, is a factor that weighs against inclusion of a product on the WHO Model List, although it may be outweighed by other factors. The more expensive the medicine, the less likely it will be placed on the WHO Model List. But it is precisely because medicines are priced beyond the reach of many in the developing world that recourse to compulsory licensing may be necessary, in order to obtain lower-cost generic medicines. It would be perverse to base a schedule of products in Bill C-9 on a list that already reflects a bias against some of the medicines most likely to be both needed and unaffordable.

Fourth, the WHO has not supported the approach of a restricted list of products in the implementation of the WTO Decision of 30 August 2003. In fact, its statements point in the opposite direction:

- In November 2003, in its only official statement to date specifically commenting on Canada's initiative to amend the Patent Act, the WHO has spoken in general terms simply of "medicines", with no suggestion that it approves of Canada's legislation being limited only to specific pharmaceutical products.[28]

- Earlier, in September 2003, the WHO issued a formal statement regarding the WTO Decision of 30 August 2003, which Canada's Bill C-9 is supposed to implement. In that statement, the

[27] World Health Organization, Essential Drugs and Medicines Policy Department, at http://www.who.int/medicines (accessed 21 February 2004).

[28] Statement of the World Health Organization on Canada's proposed legislative changes for medicines, 7 November 2003, available at: www.who.int/mediacentre/statements/2003/statement14/en/print.html.

WHO expressly stated that: "The agreement covers all medicines. Among the diseases that could be more effectively tackled as a result of this decision are AIDS, tuberculosis and malaria." In addition, the WHO stressed that: "For the agreement to have the intended impact on public health, countries will need to review the full range of medicines required from multiple suppliers, including generic producers, when making purchasing decisions."[29]

Finally, the proposal for a limited list of products may reflect a concern about an overly broad use of the system created by the WTO Decision of 30 August 2003. But presumably the Government of Canada will know whether it is abusing its own legislation, so this cannot be the concern. Should the situation arise in which Canada is concerned about an importing country abusing the legislation to import products that clearly do not address "public health problems", it would be open to Canada to amend its legislation in response.

It is, however, premature to impose a restricted list from the outset, absent any indication that abuse of a more open system is likely; it is better, in the circumstances of grave need for more affordable medicines for a wide range of public health problems, to err on the side of comprehensiveness by avoiding any restrictive list. This respects other countries' determinations as to which public health problems they choose to address through importing Canadian generic pharmaceuticals made under compulsory licence. In this regard, recall that the Doha Declaration (para. 5b) expressly reaffirmed that countries were free to determine the grounds upon which compulsory licences may be granted, and the very purpose of the WTO Decision of 30 August 2003 was to overcome the difficulty that some countries face in "making effective use" of compulsory licensing.

> "We strongly urge the Canadian government to move quickly to implement its decision to change the Patent Act. Furthermore, in light of the recent agreement at the WTO and the myriad public health needs in many countries, we also believe that the Canadian government should not impose any restrictions on the range of medicines that are eligible for export. To do so would be to renege on the WTO agreement Canada has just endorsed.
>
> As physicians, we cannot countenance the notion that Canada would tell our colleagues in developing countries, and their patients, that more affordable generic medicines can be had only to treat some conditions and not others. In our view, this is not only contrary to the spirit and letter of our international commitments, it is also an unethical approach to health policy and to health care."
>
> *- Joint statement from over 100 Canadian and international physicians, health professionals and medical students, October2003*

Furthermore, the WTO Decision of 30 August 2003 itself already addresses any concern that other WTO Members might have with regard to the "abuse" of Canadian legislation. When the Decision was adopted, it was complemented by a Statement of the Chairperson of the WTO General Council setting out "shared understandings" of WTO Members. That Statement says:

- Members recognize that the system that will be established by the Decision should be used in good faith to protect public health." The WTO itself has expressed its view that the

[29] Statement of the World Health Organization on WTO access to medicines decision, 1 September 2003, available at: www.who.int/mediacentre/statements/2003/statement10/en.

Chairperson's Statement is meaningful, saying that it "is designed to provide comfort to those who feared that the decision might be abused and undermine patent protection."[30]

- In addition, the Chairperson's Statement says that "[a]ny Member may bring any matter related to the interpretation or implementation of the Decision… to the TRIPS Council for expeditious review, with a view to taking appropriate action". Furthermore, "[I]f any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General [of the WTO] or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution." If a situation were to arise in which a WTO Member had reason to complain about an "abuse" of Canada's legislation, the WTO provides a forum in which those concerns may be addressed.

Therefore, the WTO Decision of 30 August 2003 and the accompanying Chairperson's Statement already provide adequate protection against the possibility of a WTO Member mis-using the system. This removes any need for a closed or limited list of pharmaceutical products for "public health problems" that may be subject to compulsory licensing in Canada for export in response to a need identified by an importing country.

3. Exclusion of non-WTO countries from Bill C-9 (Schedule 3)

Under Bill C-9, all "least-developed countries" (LDCs) are eligible to import generic medicines from Canadian producers, whether or not they belong to the WTO. These LDCs are listed in Schedule 2.

But Schedule 3, which lists developing countries – other than "least-developed" ones – that are also eligible to import generic medicines from Canada, only includes WTO members. Developing countries that do not belong to the WTO are excluded from being able to contract with Canadian generic manufacturers to obtain lower-cost medicines.

People in all developing countries should have access to affordable medicines regardless of whether their country belongs to the WTO. Countries such as Viet Nam, East Timor, Lebanon, Uzbekistan and many others struggle with low per capita income, high levels of poverty, and many public health needs, but do not belong to the WTO. Patients in those countries should also benefit from this important legislation. Furthermore, Canada's international human rights obligations are not limited to realizing the right to the highest attainable standard of health only in countries that join the WTO. An international decision has been taken, by all WTO Members, to relax the restrictions in TRIPS on using compulsory licensing to export lower-cost generic pharmaceuticals. There is nothing in WTO law the prevents Canada from sharing the benefit of this development with non-WTO countries, and Canada's human rights obligations do mandate such assistance.

We therefore recommend that all developing countries, whether they belong to the WTO or not, should be covered under Schedule 3 of Bill C-9. Please see Appendix II for a list of some countries that should be added to Schedule 3.

[30] WTO News, "Decision removes final patent obstacle to cheap drug imports", News release, 30 August 2003, WTO Doc. Press/350/Rev.1, at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

4. Excluding NGOs from obtaining generic pharmaceuticals for patients

In order to get a licence to supply medicines for use in a developing country, the Canadian generic manufacturer must file certain information with the Commissioner of Patents. Section 21.04(2)(f) says that the manufacturer must file the terms of its contract with "the government" of that country or "agent of that government."

While it is critical that governments strengthen access to health care in the public sector, we cannot overlook the crucial role that UN agencies and non-governmental humanitarian relief organizations play in the delivery of health care services in developing countries – including operating clinics, hospitals and other treatment sites. These organizations purchase medicines from pharmaceutical companies (both brand-name and generic) and need lower-cost supplies for their patients.

> "I have access to antiretroviral treatment and treatment for opportunistic infections, thanks to an NGO. … Before now we didn't talk about access to medication in Africa. Now we can say that at some point in the future it will come. We are dying of HIV and AIDS, and I appeal to governments, NGOs and donor agencies to put their weight behind antiretroviral treatment."
>
> *- Djeneba Coumare, woman living with HIV/AIDS in Mali, December 2003*

Bill C-9 should acknowledge this reality. A non-governmental organization (NGO) may be entitled, under the laws of the country where it works, to import and use generic versions of a medicine for its patients – either because the medicine is not patented in that country or because the NGO has obtained the necessary licence from a court or appropriate government authority.

If this is the case, then it should be able to contract directly with a Canadian generic producer to obtain the medicine, without having to enter into some form of agency agreement with a government in order to continue fulfilling their mission of delivering health care to poor patients in need. This may not be practicable or desirable in some cases, nor should NGOs be subject to political interference or favouritism by governments that could arise from a requirement to be approved as a "government agent" in order to obtain lower-cost generic medicines from Canadian suppliers.

The example of Myanmar (Burma)

Myanmar (Burma) is a WTO Member and is recognized by the UN as a "least-developed country" (LDC). But it is the only LDC that has been excluded from Schedule 2 of Bill C-9 as a country eligible to import Canadian-made generic pharmaceuticals. This is, apparently, a reflection of larger Canadian government policy toward the illegitimate military regime currently in power in Myanmar. This situation is but one example illustrating the importance of non-governmental organizations being able to source cheaper pharmaceuticals directly from generic manufacturers, rather than having the government act as gatekeeper. The non-governmental humanitarian organization Médecins Sans Frontières currently operates projects in Myanmar through which it delivers health care, including providing medicines. Given the Canadian government's legitimate refusal to deal with the current regime in Myanmar, it would be counter-productive to also block off NGOs' direct access to generic pharmaceuticals needed to treat people in one of the world's poorest countries.

5. Balancing safety and access: Comments on the proposed amendments to the Food and Drugs Act

Bill C-9 proposes to amend not only the Patent Act but also the Food and Drugs Act. Currently, the Food and Drugs Act (s. 37) states that its requirements do not apply to any drug or device that is not manufactured for consumption in Canada and not sold for consumption in Canada, as long as the package is marked as being for "Export" and a certificate has been issued stating that the package and its contents do not contravene any known requirement of the law of the country to which it is to be sent.

Despite this long-standing practice, Bill C-9 proposes to make the requirements of the Food and Drugs Act and accompanying regulations applicable to pharmaceutical products that are manufactured for the purpose of being exported in accordance with the WTO General Council Decision of 30 August 2003. This proposal requires careful consideration, so as to properly balance competing ethical considerations.

The Canadian HIV/AIDS Legal Network does not object, in principle, to requiring all reasonable efforts to ensure that pharmaceutical products being exported are of good quality, safe, and effective for the intended recipients. Indeed, as a general proposition, it would be unethical to accept that medicines and other products destined for patients in other countries should be of lower calibre than those deemed by the federal government regulator to be safe and effective for Canadians to use. The Legal Network firmly opposes any system that would pose a significant risk of supplying medicines and other products of substandard quality to patients in countries importing generic products from Canada.

However, the global inequity in access to medicines and other health products is staggering, as is the sheer magnitude of the need – and, in the case of some products, applying the same regulatory conditions as would be applied to those destined for the Canadian market will frustrate access to some of the medicines that would be most needed and useful in developing countries.

The Legal Network therefore recommends that some flexibility in our approach is required if this initiative is to clear the way for getting desperately needed, lower-priced pharmaceuticals to patients in need. The Network proposes that a realistic balancing of risks and benefits, informed by this desperate need, must inform Canada's approach to amending the Food and Drugs Act via Bill C-9.

Before approving any given medicine or other pharmaceutical product for sale, every national drug regulatory authority must weigh, on the basis of the best available evidence, the risks and benefits

Global opinion

"The Canadian government will be setting a precedent and must ensure that the amendment to their Patent Act is broad and flexible, and does not incorporate any restrictions that contravene efforts to increase access to medicines for sick and dying people."

- Joint statement on Canada's efforts to amend the Patent Act to increase access to generic medicines, 1 October 2003 , signed by over 70 civil society organizations from countries such as China, Germany, Colombia, South Africa, the UK, Canada, Kenya, Thailand, the US, Nigeria and Italy

associated with that product, in light of its intended and foreseeable use in that country's particular context. Thus, given different contexts, the national regulator in one country may make a different assessment than the regulator in another country, where the context may be quite different. A product may be approved for sale in one country but not in another.

The example of "fixed-dose combinations" of ARVs to treat HIV/AIDS

The Legal Network wishes to highlight the case of "fixed-dose combinations" (FDCs) of anti-retroviral drugs as a particularly important example of how insistence on setting the regulatory bar too high may hinder the effectiveness of Bill C-9 to increase developing countries' access to generic medicines.

Optimal therapy for people living with HIV/AIDS consists of "combination therapy" – that is, a combination of several different anti-retroviral drugs (ARVs), sometimes from different classes of ARVs (i.e., drugs that operate at different stages of the viral replication cycle) so as to increase the therapeutic benefit and reduce the likelihood of the virus mutating into drug-resistant forms. In wealthy countries such as Canada, combination therapy is now the standard of care, and the introduction of this "highly active antiretroviral therapy" (HAART) has led to dramatic reductions in morbidity and mortality among people living with HIV/AIDS in developed countries.[31] Similar benefits have been witnessed where patients have access to HAART in developing countries; the case of Brazil, which has introduced the most widespread and comprehensive program of free access to ARVs,[32] is a leading example, but others have also been documented.[33]

However, even in wealthy countries, it can be difficult for people living with HIV/AIDS to adhere to what can be complex daily drug regimens for not only combining different ARVs but also managing side effects through the use of other medications or other therapies. Efforts are underway to develop various "fixed-dose combinations" that combine two or three drugs into a single tablet, thereby reducing the number of pills that must be taken on a daily basis and the frequency of dosing.

To be of greatest benefit, ARVs must be available in fixed-dose combinations. They are particularly important for use in resource-poor settings, where infrastructure is often lacking and simplified treatment regimens are critical. Non-governmental organizations such as Médecins Sans Frontières (MSF) have identified the critical need for FDCs based on the experience of delivering ARV treatment

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[31] CASCADE Collaboration. "Determinants of survival following HIV-1 seroconversion after the introduction of HAART." *The Lancet* 2003; 362: 1267-74, and references therein.

[32] *AIDS: the Brazilian Experience*, Ministry of Health of Brazil, Brasília 2001; P.R. Teixeira, M.A. Vitória, J. Barcarolo, "The Brazilian Experience in Providing Universal Access to Antiretroviral Therapy", in *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries – Issues and Challenges* (Paris: Agence Nationale de Recherches sur le SIDA, June 2003); J. Galvão, "Access to antiretroviral drugs in Brazil", *The Lancet*, 2002; 360: 1862-65. See also the early, classic article by Tina Rosenburg, "Look at Brazil: Patent laws are malleable. Patients are educable. Drug companies are vincible. The world's AIDS crisis is solvable," *New York Times Magazine*, 28 January 2001 (at http://www.nytimes.com/library/magazine/home/20010128mag-aids.html).

[33] E.g., Paul Farmer et al., "Community-based approaches to HIV treatment in resource-poor settings", *The Lancet* 2001; 358: 404-409; J.S. Mukherjee et al., "Tackling HIV in resource poor countries", *British Medical Journal* 2003; 327: 1104-1106.

in resource-poor settings, such as the treatment projects operated by MSF in over twenty countries.[34] The World Health Organization (WHO) has recognized that FDCs are a key element in global efforts to scale up AIDS treatment in developing countries. The WHO has recommended FDCs in its treatment guidelines[35] and has "pre-qualified" several FDCs produced by generic companies as meeting international standards and guidelines on the quality and safety of medicines.[36]

But patents hinder access to FDCs, because different companies usually hold the patents on different drugs. This limits the potential therapeutic benefits of combining different companies' drugs into fixed-dose combinations, because a company can only manufacture a FDC that combines its own drugs.

The bioavailability of a pill you can't get is zero.

As a result, there is not yet any brand-name product approved for the Canadian market that combines anything other than the ARVs patented by a single company. Only two "fixed-dose combinations" have been produced by an originator company: Combivir® combines, in a single pill, the drugs lamivudine (3TC) and zidovudine (AZT), both of which are patented by GlaxoSmithKline (GSK), while Trizivir® combines these two drugs with a third drug, abacavir, that is also patented by GSK. (These two FDCs are approved for sale in Canada.) All other existing FDCs combine drugs the patents on which are held by different originator companies – meaning they are produced by generic drug manufacturers that are not currently blocked by patents from manufacturing generic versions of these medicines, including in combination – such as Indian generic companies currently producing ARVs.

Therefore, in the absence of "fixed dose" combinations of patented medicines having been approved for sale in the Canadian market, we are concerned about an inflexible requirement that a generic producer's fixed dose combination of different generic drugs meet the same standards as if it were to be marketed in Canada. In the absence of an existing "Canadian reference product" against which the generic producer's FDC could be compared, requiring a full set of data from extensive clinical trials for the new, generic combination of existing patented medicines may prove an expensive, time-consuming, and ultimately insurmountable obstacle to exporting generic products combining different ARVS to the countries and settings where they are most needed. Yet we note that, in the WTO General Council Decision of 30 August 2003, WTO Members expressly recognized, "where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision".

Therefore, we urge the Committee to recommend that the regulations to be prescribed under the *Food and Drugs Act* reflect adequate flexibility in permitting the approval of generic pharmaceutical products for export in the absence of a "reference product" that has been approved for sale in Canada.

[34] Médecins Sans Frontières. *Two Pills a Day Saving Lives: Fixed-Dose Combinations (FDCs) of Antiretroviral Drugs*. Briefing note, MSF Campaign for Access to Essential Medicines, February 2004.

[35] Ian Grubb, Jos Perriëns & Bernhard Schwartländer. *A Public Health Approach to Antiretroviral Treatment: Overcoming Constraints* (Geneva: World Health Organization, 2003).

CONCERNS ABOUT IMPACT ON RESEARCH AND DEVELOPMENT

It has been suggested that allowing compulsory licensing to produce generics for developing world patients will somehow threaten future private sector investments in R&D by pharmaceutical companies. However, this criticism is overblown and misplaced.

It has been repeatedly confirmed that developing country markets represent a very small portion of total global pharmaceutical sales (see table below), meaning they have little impact on the R&D agenda of multinational pharmaceutical companies. Recently, this conclusion has been reaffirmed by the United Kingdom's Commission on Intellectual Property Rights, in an extensive study of the development implications of intellectual property policy.[37]

As Hollis & Flynn have recently noted, "[p]rofits to be obtained from a patent in developing countries are simply too small to create a meaningful incentive to invest in research and development for developing country markets."[38]

Indeed, while the pharmaceutical industry consistently remains, year after year, the most profitable in the world,[39] the vast majority of those profits are earned from the wealthy, developed world:

Pharmaceutical sales in the global market, 2002

Percentage of forecast revenues	Region
41.8	North America
24.8	Europe
11.3	Japan
7.5	Latin America & Caribbean
5.0	South-East Asia/China
2.6	Middle East
1.8	Eastern Europe
1.8	Indian subcontinent
1.3	Australasia
1.3	Africa
0.8	Commonwealth of Independent States

Source: IMS Health 2000, reproduced in UNDP Human Development Report 2001 (at 108).

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[36] World Health Organization. "WHO adds new fixed dose combinations to its list of quality products for AIDS treatment: Key component of 3 by 5 strategy", Geneva, 1 December 2003. For further information, see:

[37] UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, 2002.

[38] Aidan Hollis & Sean Flynn. "An Economic Analysis of Compulsory Licences for Needed Medicines", 15 December 2003. Professor Hollis is a tenured Associate Professor in the Department of Economics, University of Calgary and TD MacDonald Chair of Industrial Economics, Competition Bureau of Canada. Mr. Flynn is Senior Attorney with the Consumer Project on Technology, Washington, D.C.

[39] E.g., see "The 2002 Fortune 500", *Fortune Magazine*, April 2002.

Issuing compulsory licences to generic manufacturers to produce pharmaceutical products exclusively for export to developing and least-developed countries will not seriously affect the profitability of patent-holding pharmaceutical manufacturers nor their research and development agenda.

CONCLUSION

If done correctly, and in a spirit of good faith that truly aims to assist countries lacking pharmaceutical manufacturing capacity to make effective use of compulsory licensing to address public health problems, this Canadian initiative can set a welcome global precedent.

The initiative has attracted the support of Canadians, who welcome the opportunity to make a concrete contribution to the global response to health crises such as HIV/AIDS. But as the comments below and on the next page demonstrate, Canadians have also noted that Bill C-9 must be significantly improved if that contribution is to be realized.

Canadian civil society: shared concerns about Bill C-9

The shortcomings [in the bill] represent serious flaws that will undermine the effectiveness of Canada's initiative. … With this legislation, Canada becomes the first country to take steps to implement the WTO decision and its initiative has received worldwide attention. It is, therefore, critical that Canada's initiative set a worthy global precedent that will make a concrete contribution to saving and extending lives in the developing world. Canadians have heard many promises that Bill C-56 [now Bill C-9] will offer meaningful assistance to developing countries facing public health problems. Canadians want to see those promises realized.

- Joint letter to Prime Minister Paul Martin, of 13 January 2004, signed by:

Canadian HIV/AIDS Legal Network
Oxfam Canada
Canadian Council for International Co-operation
Interagency Coalition on AIDS and Development
The North-South Institute
Students Against Global AIDS
Médecins Sans Frontières
Canadian Labour Congress
Rights & Democracy
CARE Canada
World Vision
McGill International Health Initiative

What Canadians think:

"Bill C-56 is ground-breaking legislation, so Canada has lots to be proud of, but first let's make sure we get it right for the benefit of those who are dying from the lack of these drugs."

- Catherine Little, Calgary, *Globe & Mail*, 17 February 2004

"The initial Bill C-56 died when Parliament prorogued in November. And from what I've seen of the old bill, it was probably a good death as there were several major flaws in it that would frustrate the process and embarrass us internationally."

- Dr. Robert C. Dickson, Calgary, *Daily Herald* (Prince Albert), 14 February 2004

"It is unethical to withhold cheaper medicines from poor people in a country because it does not belong to the WTO."

- Glen Bradford, *The Vancouver Sun*, 11 December 2003

"With the first reading of Bill C-56 in November, Canada became the first country with a well-developed generic pharmaceuticals industry to begin implementing the WTO Decision [of 30 August 2003]. The final form of this legislation may well prove to be a model for others to follow; all the more important, then to get the model right.

It is sad, therefore, to see on closer scrutiny a piece of legislation that may prove to be more restrictive than the WTO deal itself, and less progressive in spirit than the Doha declaration of November 2001, which prepared the ground."

- Editorial, *Canadian Medical Association Journal*, 9 December 2003

"No government calling itself Liberal would dare renege on a commitment to put the needs of the sick and dying ahead of the commercial interests of multinational drug companies."

- Geoffrey Stevens, *The Record* (Waterloo Region), 17 November 2003

"As one of the first countries to prepare this legislation, it is critically important that Canada follows the course set in Geneva – i.e. that it adopts the high WTO standard – and takes the direction which allows countries to meet their public health objectives. To do so is fully consistent with our commitment to health as a development priority. To do otherwise will dash the expectations of many Canadians and millions more in the developing world. Canada will have failed not only to live up to the WTO Decision, but also will have missed a critical opportunity to protect global health. In fact, rather than attracting congratulations for its leadership, Canada will be severely criticized for action which undermines the WTO and public health."

- Ann Weston, Vice-President, North-South Institute, Ottawa, 21 October 2003

ABOUT THE CANADIAN HIV/AIDS LEGAL NETWORK

The Canadian HIV/AIDS Legal Network is based in Montréal (Québec), Canada. It is the only national, community-based organization in Canada working exclusively in the area of policy and legal issues raised by HIV/AIDS. It was formed in November 1992 and has over 250 members across Canada and internationally.

The Network is a charitable organization engaged in education, legal and ethical analysis, and policy development. We promote responses to HIV/AIDS that:

- implement the *International Guidelines on HIV/AIDS and Human Rights*
- respect the rights of people with HIV/AIDS and of those affected by the disease
- facilitate HIV prevention efforts
- facilitate care, treatment, and support of people with HIV/AIDS
- minimize the adverse impact of HIV/AIDS on individuals and communities
- address the social and economic factors that increase vulnerability to HIV/AIDS and to human rights abuses

We produce, and facilitate access to, accurate and up-to-date information and analysis on legal, ethical, and policy issues related to HIV/AIDS, in Canada and internationally. We consult, and give voice to, Network members and a wide range of participants, in particular communities of people with HIV/AIDS and those affected by HIV/AIDS, in identifying, analyzing, and addressing legal, ethical, and policy issues related to HIV/AIDS. We link people working on or concerned by these issues. We recognize the global implications of the epidemic and incorporate that perspective in our work.

APPENDIX I
SUMMARY OF PROPOSED AMENDMENTS TO BILL C-9

The Canadian HIV/AIDS Legal Network proposes that numerous sections in Bill C-9 be amended so as to fully and faithfully implement the WTO General Council Decision of 30 August 2003, in a fashion that accords with the letter and the spirit of the Declaration on the TRIPS Agreement and Public Health (Doha, November 2001). The amendments below will improve Bill C-9 and help it achieve the objective of increasing access to more affordable medicines and other pharmaceutical products for patients and countries in need.

The Legal Network therefore recommends the amendments that are shown below, involving deletions of some text, and the addition of text to existing provisions and, in some cases, the addition of new provisions. Recommended deletions are shown in text that has been struck through (e.g., ~~text~~) and text to be added has been underlined (e.g., <u>text</u>). Each proposed revision is followed by a short commentary explaining the recommendation; this supplements the submissions made above. The recommendations are presented in the same order as the provisions in the bill.

SECTION IN BILL C-9	RECOMMENDED AMENDMENTS
21.01 *reflecting the Doha Declaration and WTO Decision of 30 August 2003 in the purpose clause*	**Add the following underlined text:** **The purpose of sections 21.02 to 21.17 is to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, <u>by enabling countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make effective use of compulsory licensing.</u>** Comment: The Doha Declaration (para. 6) committed WTO Members to find a solution to the problem that countries with insufficient pharmaceutical manufacturing capacity face difficulty "in making effective use of compulsory licensing" under TRIPS. The WTO Decision of 30 August 2003 is the "solution" to this problem adopted by WTO Members. The purpose of Canada's Bill C-9 is to implement that WTO Decision. This should be reflected in the statement of purpose accompanying the amendments to the Patent Act.
21.03(1)(a) *Schedule 1 list of products*	**Delete this subsection.** Comment: We have recommended that Schedule 1 (list of products that may be subject to compulsory licensing) be removed from the bill entirely. Consequently, there is no need for subsection 21.03(1)(a) regarding the power of the Governor in

	Council to amend said schedule.
21.03(1)(c) *including non-WTO countries on Schedule 3 as potential importers*	**Add the following underlined text:** **"Schedule 3, by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, <u>or by adding the name of any country that is not a WTO Member that has identified itself as a developing country.</u>"** Comment: Appendix II provides a (non-exhaustive) list of countries that should be added to Schedule 3 of Bill C-9.
s. 21.04(2)(f) *recognizing NGOs may contract directly with generic pharmaceutical producers*	**Add the following underlined text:** **"the contractual terms and conditions of the agreement between the person and the government of the country or WTO Member, ~~or~~ the agent of that government, <u>or other purchaser legally entitled to import and distribute the product in the country or WTO Member</u>, under which the pharmaceutical product referred to in paragraph (b) is to be manufactured and sold for export."** Comment: This amendment would make explicit that non-governmental and international organizations, such as UN agencies and humanitarian relief organizations, can contract directly with Canadian producers for lower-cost generic pharmaceutical products. If the intent of the Government of Canada is to include, within the term "agent of government", NGOs as possible purchasers of generic pharmaceuticals made under compulsory licence in Canada, then it would be preferable to avoid any confusion by making this explicit in the legislation.
Section 21.04(3)(a)(ii) *compulsory licence issued by legally competent authority in a Schedule 2 least-developed country that is a WTO Member*	**Add the following underlined text:** **"a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence, <u>or confirming that such a licence has been granted in the WTO Member by the appropriate authority,</u> to use the invention pertaining to the product;"** Comment: Bill C-9 should not require that the compulsory licence be granted by the government in the country to which the product is being imported. Rather, in accordance with the WTO's August 2003 decision, it should also recognized that a compulsory licence may have been issued by another authority that is competent,

	under the laws of the importing country, to do so. All that should be required is confirmation, in the form of an official notice by the government of that country, that a legally competent authority has granted a compulsory licence authorizing importation of the product. The purpose of the legislation is to enable the "effective use" of compulsory licensing in countries with no or insufficient pharmaceutical manufacturing capacity so as to obtain less expensive pharmaceutical products. All countries, including those that are WTO Members and are therefore bound by the TRIPS Agreement, are free to provide for compulsory licensing in their domestic law. For those that bound by the TRIPS Agreement, they must respect certain standards in providing for compulsory licensing (which are set out in Article 31 of the TRIPS Agreement). But they are free to implement this provision in their own law as they see fit. What this means is that countries can determine which authority or authorities are competent, in their legal system, to issue compulsory licences and set the terms of those licences. It may be a government official (e.g., the Minister of Health in the case of pharmaceutical patents, the Minister of Defence in the case of patents on products used for defence purposes, etc). Or, it may be another competent authority, such as a court (e.g., South Africa) or a quasi-judicial officer (e.g., the Controller of Patents in India, the Commissioner of Patents in Canada, etc.) If the competent authority in the importing country has issued a compulsory licence allowing the licence holder to import and distribute the product in that country, there is no reason for Canadian law to insist on anything more than official confirmation of that fact.
21.04(3)(b)(ii) *licence issued by competent authority in a Schedule 2 least-developed country that is <u>not</u> a WTO Member*	**Add the following underlined text:** **"a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence, <u>or confirming that such a licence has been granted in the country by the appropriate authority</u>, to use the invention pertaining to the product;"** Comment: Same as with previous recommendation.
21.04(3)(c)(ii) *licence issued by competent authority in a Schedule 3 developing country, including*	**Add the following underlined text:** **"if the product is patented in that <u>country or</u> WTO Member, a certified copy of the notice in writing that the <u>country, if not a WTO Member, has provided to the Government of Canada through diplomatic channels, or if a WTO Member,</u> that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence<u>, or confirming that such a licence has been granted in the</u>**

countries which are not WTO members	**<u>country or WTO Member by the appropriate authority,</u> to use the invention pertaining to the product; and;"** Comment: Same as with previous recommendation. Note also that this subsection needs to be amended to reflect our recommendation that Schedule 3 be amended to include developing countries which are not WTO Members.
21.04(6)(a) *"right of refusal" in the case where there is only one patentee*	**Delete this subsection entirely:** **~~(a) will supply the pharmaceutical product to the country or WTO Member named in the notice on terms and conditions that are no less favourable than those referred to in paragraph 2(f); or~~** Comment: This section would give the company holding the patent on a pharmaceutical product the "right" to scoop contracts that generic producers have negotiated to supply products at lower prices to purchasers in developing countries. (And under the s. 21.05(5) proposed in Bill C-9, if the company with the patent exercises this "right", the generic producer is blocked from getting any licence at all.) This flaw goes to the very heart of the legislation. If this section stays in Bill C-9, generic producers will have no incentive to even negotiate contracts with countries in need of cheaper medicines. In the absence of any competitive pressure, companies holding patents will also have little reason to lower their prices. Patients in developing countries will be unlikely to gain access to more affordable medicines. Bill C-9 will be meaningless.
21.04(7)(a) *"right of refusal" in the event there is more than one patentee*	**Delete this subsection entirely:** **~~(a) one or more of the patentees provide the Commissioner, within thirty days after the statement is sent, with a solemn or statutory declaration in the prescribed form stating that the patentee, or an agent of the patentee, will supply the pharmaceutical product to the country or WTO Member named in the notice on terms and conditions that are no less favourable than those referred to in paragraph 2(f);~~** Comment: This subsection grants the "right of refusal" in the situation where there is more than one patentee named in the notice of intent. Same rationale as for the previous recommendation regarding the parallel provision in subsection 21.04(6).

21.04(8) *new section to be added to deal with situations of national emergency, other circumstances of extreme urgency, or public non-commercial use, and use of compulsory licensing to remedy anti-competitive practices*	**Add the following text as a new s. 21.04(8):** **21.04(8) (a) Subsections (5), (6) and (7) do not apply if the notice of intent relates to a country that is not a WTO Member, or in the case of a country that is a WTO Member, if the Commissioner receives a certified copy of a written statement, provided by the WTO Member, confirming that** **(i) in the case of a WTO Member listed in either Schedule 2 or 3, the product is to be used for addressing a national emergency or other circumstances of extreme urgency, or is for public non-commercial use;** **(ii) in the case of a WTO Member listed in Schedule 4, the product is to be used for addressing a national emergency or other circumstances of extreme urgency; or** **(iii) in the case of any WTO Member, that the importation and distribution of the product in that WTO Member has been permitted in that Member to remedy a practice by the patentee that has been determined by the appropriate judicial or administrative process in that Member to be anti-competitive.** **(b) If the applicable requirements in paragraph (a) are satisfied, the Commissioner shall, without delay, send to each patentee named in the notice, by registered mail, a copy of the notice of intent and of the written statement, if required, and shall proceed to issue the authorization applied for in accordance with the other provisions of this Act.** Comment: In accordance with the TRIPS Agreement and the WTO Decision of 30 August 2003, this new section would properly reflect the rights of WTO Members to waive, in certain circumstances, the requirement of attempting to negotiate a voluntary licence with a patent holder before resorting to compulsory licensing. Under Article 31 of the TRIPS Agreement, every WTO Member is entitled to use compulsory licensing. The Doha Declaration on the TRIPS Agreement and Public Health reaffirmed this right and that each WTO Member has "the freedom to determine the grounds upon which such licences are granted." Under Article 31(b) of TRIPS, ordinarily a compulsory licence may only be issued if efforts have first been made to obtain a voluntary licence from the patent holder "on reasonable commercial terms and conditions" and those efforts "have not been successful within a reasonable period of time."

	However, TRIPS Article 31(b) also provides that this requirement "may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use", and simply requires that the patent holder be notified "as soon as reasonably practical" (in situations of national emergency or other circumstances of extreme urgency) or "promptly" (in the case of public non-commercial use). In addition, TRIPS Article 31(k) also waives this requirement of prior negotiation with the patent holder if a compulsory licence is being issued to remedy a practice by the patent holder that a judicial or administrative process has determined is anti-competitive. In the WTO Decision of 30 August 2003, WTO Members agreed that countries using the system to import pharmaceutical products may notify that they would use the system in only a limited way, "for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." Indeed, in conjunction with the adoption of the 30 August 2003 decision, some WTO Members (those listed in Schedule 4 of Bill C-9) formally stated that they would only use the system to import pharmaceuticals produced under compulsory licences in situations of national emergency or other circumstances of extreme urgency. Those WTO Members have not reserved the right to use the system to import in other circumstances (such as for public non-commercial use). This proposed new section would reflect this limitation, while still allowing them to fully exercise their right to make effective use of compulsory licensing, without delay, in such urgent circumstances. In the case of all other WTO Members (i.e. those listed in Schedules 2 and 3), under the WTO Decision of 30 August 2003, they are entitled to use compulsory licensing to import generic pharmaceuticals in accordance with the original provisions of TRIPS Article 31(b) – meaning that, in circumstances of national emergency, other circumstances of extreme urgency, or in cases of public non-commercial use, there is no TRIPS requirement to first make efforts to negotiate a voluntary licence with the patent holder. This proposed new section would allow them to fully exercise their rights to make effective use of compulsory licensing, without delay, in these situations and for these purposes. *We note that the WHO has recently reiterated that the global lack of access to ARVs to treat HIV/AIDS is a global emergency.* In the case of anti-competitive practices by a patent-holder, all WTO Members remain entitled to use compulsory licensing, without prior efforts to negotiate a voluntary licence with the patent holder, to remedy such practices. The WTO Decision of 30 August 2003 allows Canada to permit compulsory licensing for export to importing countries that have used compulsory licensing at their end, in accordance with the TRIPS Agreement, to remedy anti-competitive practices. The proposed amendment above would reflect this in Bill C-9.

	Countries that are not WTO Members are not bound by any limitations on their use of compulsory licensing, since TRIPS does not apply to them. Therefore, they are not bound by the general requirement in TRIPS to first make efforts to negotiate a voluntary licence. With respect to these countries, simple notification that a compulsory licence has been issued by a legally competent authority in that country should suffice for the purposes of Canadian generic manufacturer obtaining the necessary licence to export. This fully respects Canada's international legal obligations under TRIPS and respects the sovereignty of other countries determining when to use compulsory licensing to address public health problems.
21.05(1) *specifying a time frame within which Commissioner must decide whether to issue authorization*	**Add the following underlined text:** **"Subject to subsections (3) to (5), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, and in any event no later than 15 days from the date on which all statutory or other prescribed requirements regarding the application have been satisfied, authorize the use of a patented invention by that person solely for the purposes of manufacturing the pharmaceutical product named in the application and selling it for export to the country or WTO Member named in the application."** Comment: Reflecting the urgency and gravity of the need for more affordable medicines in countries that would use this system to import generic products from Canada, this amendment would ensure that the Commissioner's decision about issuing a licence to the generic manufacturer is made in a timely fashion once all the required information has been filed and other requirements (such as the notification from the Minister of Health contemplated in section 21.05(3)) have been satisfied.
21.05(5)(a) and 21.05(5)(b) *eliminating the "right of refusal" that blocks Commissioner from issuing a licence*	**Delete the references in these two sub-paragraphs to the current paragraphs 21.04(6)(a) and 21.04(7)(a), as follows:** **(a) in the case where only one patentee was named in the notice of intent, the patentee has provided the Commissioner with the solemn or statutory declaration referred to in paragraph ~~21.04(6)(a) or~~ (b) within the time provided in that subsection;** **(b) in the case where more than one patentee was named in the notice of intent, ~~one or more of the patentees have provided the Commissioner with the solemn or statutory declaration referred to in paragraph 21.04(7)(a), or~~ all of the patentees have provided the Commissioner with the solemn or statutory declaration referred to in paragraph 21.04(7)(b), within the time provided in that subsection.** Comment: We have recommended the deletion from the bill of sub-paragraphs 21.04(6)(a) and 7(a). Consequently, the corresponding references to those sub-paragraphs should also be removed from subsection 21.05(5).

21.08 *new provisions allowing the patentee to seek a variance in the royalty in the event a compulsory licence is issued by the Commissioner*	**Add the following new subsections to s. 21.08:** **(3) In the circumstance where the authorization has been granted by the Commissioner a patentee may, within 30 days of receiving a copy of the authorization, deliver to the Commissioner a statement verified by statutory declaration fully setting out the grounds on which the patentee requests that the Commissioner vary the royalty to be paid by the holder of the authorization, after serving a copy of said statement on the holder of the authorization.** **(4) If a patentee files a statement as referred to in subsection (3), the holder of the authorization or any other interested party shall have 30 days within which to file a response to the statement with the Commissioner, which response must be served upon the patentee.** **(5) Within 30 days of the expiry of the response period referred to in subsection (4), the Commissioner shall issue a decision on the request for varying the royalty, which decision shall take effect immediately.** **(6) In the event that the royalty is varied by the Commissioner pursuant to a request by a patentee under subsection (3), the maximum royalty that may be ordered by the Commissioner shall be an amount equal to four percent of the value of the pharmaceutical products exported under the authorization, said value to be determined as set out in subsection (2).** **(7) The Governor in Council may prescribe the grounds upon which a patentee may make a request that the royalty be varied and may prescribe the factors to be considered by the Commissioner in ruling on such a request, including such factors as:** **(a) the humanitarian purpose of facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries;** **(b) the degree to which the invention covered by the patent was developed with public funds;** **(c) the degree of utility, novelty and importance of the invention;** **(d) the cost to the patentee of developing the invention or acquiring the patent;** **(e) the need for adequate incentives for the creation and commercialization of new inventions;** **(f) the interests of the public as patients and payers for health care;**

(g) the public health benefits of expanded access to the invention;

(h) the need to remedy anti-competitive practices;

(i) the remuneration, if any, already awarded in the country to which the product manufactured under the authorization is to be exported; or

(j) other public interest or other considerations as may be prescribed.

(8) The decision of the Commissioner under subsection (5) may be judicially reviewed upon application, by any interested party, to the Federal Court, whose judgment, decision or order is final.

Comment: Under Article 31(h) of the TRIPS Agreement, in the event of a compulsory licence being issued, the patent holder is entitled to be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." Under TRIPS Article 31(j), any decision relating to the remuneration provided in the case of a compulsory licence "shall be subject to judicial review or other independent review by a distinct higher authority in that Member."

The new sections we propose would provide greater protection for these entitlements of patent holders than is currently the case in Bill C-9. At the same time, they would ensure the system put in place by Bill C-9 is functional and provides reasonable certainty to both patentees and generic producers, while also ensuring that disputes over the appropriate royalty do not delay the issuing of a compulsory licence and the timely production of urgently needed pharmaceuticals for export to developing countries.

It should be noted that, under TRIPS Article 1.1, WTO Members "shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." Furthermore, the WTO Decision of 30 August 2003 recognizes the "importance of a rapid response" to the needs of importing countries seeking to obtain pharmaceutical products produced under compulsory licences in accordance with the WTO Decision. All WTO Members have adopted these two instruments.

The new provisions we recommend for inclusion in Bill C-9 would:

- set firm timelines for the process of obtaining the necessary licence for manufacturing and exporting generic pharmaceuticals from Canada to importing countries needing cheaper pharmaceuticals;

- give the patentee a "reasonable period of time" (i.e., 30 days) to decide whether to voluntarily issue a licence to the generic producer to allow export of cheaper medicines "on reasonable commercial terms and conditions" (i.e.,

	a royalty rate of 2%); ▪ require the Commissioner of Patents to fix an "adequate remuneration" in each case where the Commissioner issues a compulsory licence; ▪ establish a presumption that a royalty rate of 2% is appropriate in the circumstances of compulsory licensing for export to developing countries, but still grant the patentee an opportunity to seek a different royalty rate other than the 2% rate that applies in the case of a voluntary licence; ▪ impose a maximum royalty rate of 4% on a compulsory licence that authorizes manufacture of generic pharmaceuticals for export to developing countries, which provision is more than reasonable in light of past Canadian law and practice in this area when using compulsory licensing to supply the wealthier Canadian market; ▪ ensure that any dispute over the proper royalty rate does not delay the ability of the generic manufacturer to produce the pharmaceutical products for export to the developing country in need.
21.09 *term of authorization should not be limited to 2 years*	**Amend this section with the deletion shown and by adding the underlined text:** **The use of a patented invention authorized by subsection 21.05(1) is authorized for a period ~~of two years~~ <u>equal to the term of the agreement referred to in subsection 21.04(2)(*f*), or, in the Commissioner's discretion, until such time as the patent on the invention in Canada has expired,</u> or if another period is prescribed, for that other period, beginning on the date that the authorization is granted.** Comment: As Bill C-9 currently reads, the Commissioner of Patents may only issue a compulsory licence for a maximum period of 2 years. This limit is arbitrary and should be amended to allow greater flexibility in responding to the real needs of importing countries. Furthermore, a cap of 2 years operates as a disincentive to generic producers negotiating contracts with developing country purchasers, given the sunk transaction costs of doing so. Consider, for example, that the need for many medicines or other products will obviously continue well past a 2 year period, and there will likely be greater certainty and economies of scale (and hence savings) to be had if developing country purchasers and Canadian generic producers can negotiate contracts for lower-cost generic pharmaceuticals for more than simply a 2-year period. This would help foster interest by generic producers, as well as longer-term investment by importing countries in scaling up treatment programmes, thereby supporting longer-term sustainability of treatment efforts. The best option would be to allow the Commissioner the discretion to issue the

	licence for the remainder of the term of the patent on that invention in Canada; since this scheme is solely for allowing the export of generic pharmaceuticals, this fully preserves the patentee's patent rights in relation to the Canadian market. Alternatively, the Commissioner should issue a licence for the term of the contract that is the basis on which the Canadian generic producer has sought a licence to manufacture a generic product for export. Recall that, under the subsection 21.04(2)(*f*) that is proposed in Bill C-9, the generic producer must file the terms and conditions of its contract with the importing country purchaser as part of its application for a licence. It makes most sense if the licence that is issued allows the producer to follow through on that contract, rather than cutting off production and supply partway through.
21.14(d)	**Add the following underlined text:** **(d) the product exported to the country or WTO Member, as the case may be, under the authorization has been, with the <u>prior</u> knowledge <u>and express or implied consent or participation</u> of the holder of the authorization, re-exported in a manner that is contrary to the General Council Decision and in quantities that are significant, considering the quantities originally exported.** Comment: It is proper, and in keeping with the WTO Decision of 30 August 2003, that reasonable efforts be required of the generic producer to prevent diversion of the product from the country to which the product is exported. Bill C-9 provides for some such measures, including distinguishing the generic product from the brand-name product of the originator. However, it is inevitable that some such diversion may occasionally occur, notwithstanding the efforts of the generic producer and of the exporting and importing country. This may eventually come to the attention of the generic manufacturer in Canada, constituting "knowledge" of the re-exportation. But this should not be technically sufficient grounds on which terminate the license. Rather, in order for the Federal Court to revoke the licence, there should be some requirement to establish that the licence holder expressly or implicitly consented to, or participated in, that re-exportation.

APPENDIX II:
LIST OF COUNTRIES TO BE ADDED TO SCHEDULE 3

As was noted above, developing countries which do not belong to the WTO are currently omitted from Schedule 3, and therefore are unable to benefit by importing lower-cost pharmaceuticals from Canadian generic manufacturers. This restriction is not ethically defensible, nor is it mandated by any WTO texts (TRIPS Agreement, the Doha Declaration, or the Decision of 30 August 2003).

The table below shows numerous countries that are currently missing from, and should be added to, Schedule 3 of Bill C-9, in light of such factors as their ranking on the UN Development Program's "Human Development Index" , the per capita GDP, the extent of poverty in the country, or some combination of the above. Other data could and should also be considered; this table is not exhaustive.

Also shown for information are the estimated numbers of people living with HIV/AIDS, tuberculosis and malaria, as well as average life expectancy at birth. In addition, a column shows the range estimating the percentage of the population that has sustainable access to affordable "essential medicines", as may be defined in the WHO's Model List of Essential Medicines or an applicable national list. It should, of course, be noted that such lists of "essential medicines" omit many medicines needed to treat public health problems – and in any event, increased access to more affordable, generic versions of those medicines would have a positive impact on this number and would represent a step toward realization of the human right to health.

A few countries with a high HDI ranking, and some developing countries which are already included in Schedule 3 of Bill C-9, are also shown for comparison purposes. The entries for these countries have been shaded, so as to set them off from the countries that are currently omitted from Schedule 3. The table illustrates that the exclusion of many developing countries, on the basis that they are not WTO Members, is arbitrary and contrary to indicators of income or health needs.

Unless otherwise indicated, data shown on the table below is taken from the "human development indicators" compiled in the UN Development Programme's *Human Development Report 2003: Millennium Development Goals: A compact among nations to end human poverty*, available at http://www.undp.org/hdr2003. Where data was not available from UNDP, figures marked with an asterisk have been taken from the *World Factbook 2003* prepared by the US Central Intelligence Agency, available at http://www.cia.gov/cia/publications/factbook/. In some cases, neither of these sources provides data for a particular figure. All figures are in US dollars.

NOTE regarding Schedule 2: Omission of one least-developed country

We note as well that the country of Myanmar (Burma) is the only one of the 49 countries recognized by the United Nations as a "least-developed country" that does not appear on Schedule 2 of Bill C-9. This omission should be corrected by adding Myanmar to Schedule 2. If necessary, additional provisions may be put in place to ensure that patients in Myanmar can benefit from cheaper, Canadian generic pharmaceuticals while also respecting the fact that the Government of Canada does not maintain diplomatic relations with the illegitimate military regime currently in place in Myanmar.

Country	Human Development Index (HDI) Ranking	GDP per capita (PPP US$)	Population below poverty line	Population with sustainable access to affordable "essential drugs" (percentage range, WHO est.)	People living with HIV/AIDS (% age 15-49), 2001	Malaria cases (per 100,000 people), 2000	Tuberculosis cases (per 100,000 people), 2001	Life expectancy at birth (in years)
Argentina	34 (high)	$11,320	37% (2001 est)*	50-79	0.69%	1	30	73.9
Algeria	107 (medium)	$6,090	22.6%	95-100	0.1%			69.2
Azerbaijan	89 (medium)	$3,090	49% (2002 est)*	50-79	< 0.1%			71.8
Bahamas	49 (medium)	$16,270	N/A	80-94	3.5%	--	19	67.2
Bahrain	37 (high)	$16,060	N/A	95-100	0.26%	--	34	73.7
Barbados	27 (high)	$15,560	N/A	95-100	1.2%	--	11	76.9
Belarus	53 (high)	$7,620	22% (1995 est)*	50-79				69.6
Brazil	65 (medium)	$7,360	23.7% on less than $2/day	0-49	0.65%	344	44	67.8
Bosnia & Herzegovina	66 (medium)	$5,970	N/A	80-94				73.8
Canada	8 (high)	$27,130	N/A	95-100	0.31%	--	3	79.2
Chile	43 (high)	$9,190	17.0%	80-94	0.30%	--	10	75.8
Cuba	52 (high)	$5,259	41.9%	95-100	< 0.1%	--	6	76.5
Dem.P.R. Korea (North Korea)	N/A	N/A	N/A	N/A				N/A

Country	Human Development Index (HDI) Ranking	GDP per capita (PPP US$)	Population below poverty line	Population with sustainable access to affordable "essential drugs" (percentage range, WHO est.)	People living with HIV/AIDS (% age 15-49), 2001	Malaria cases (per 100,000 people), 2000	Tuberculosis cases (per 100,000 people), 2001	Life expectancy at birth (in years)
Iran	106 (medium)	$6,000	7.3% on less than $2/day	80-94				69.8
Iraq	N/A	$2,400 (2002 est)*	N/A	N/A				N/A
Kazakhstan	76 (medium)	$6,500	62% on less than $4/day 26% (2001 est)*	50-79				65.8
Lebanon	83 (medium)	$4,170	28% (1999 est)*	80-94				73.3
Libya	61 (medium)	$7,570	N/A	95-100				72.4
Malaysia	58 (medium)	$8,750	9.3% on less than $2/day	50-79	0.35%	57	67	72.8
Marshall Islands	N/A	$1,600 (2001 est)*	N/A	N/A	N/A	N/A	N/A	N/A
Micronesia (Federated States of)	N/A	$2,000 (2002 est)*	26.7%*	N/A	N/A	N/A	N/A	69.13 (2003 est)*
Mauritius	62 (medium)	$9,860	10% (2001 est)*	95-100	0.1%	1	57	71.6

Country	Human Development Index (HDI) Ranking	GDP per capita (PPP US$)	Population below poverty line	Population with sustainable access to affordable "essential drugs" (percentage range, WHO est.)	People living with HIV/AIDS (% age 15-49), 2001	Malaria cases (per 100,000 people), 2000	Tuberculosis cases (per 100,000 people), 2001	Life expectancy at birth (in years)
Nauru	N/A	$5,000 (2001 est)*	N/A	N/A				61.95* (2003 est)
Niue	N/A	$3,600 (2000 est)*	N/A	N/A				N/A
Palau	N/A	$9,000 (2001 est)*	N/A	N/A				69.5 (2003 est)*
Panama	59 (medium)	$5,750	17.9% on less than $2/day	80-94	1.5%	36	28	74.4
Russian Federation	63 (medium)	$7,100	53% on less than $4/day	50-79				66.6
Saudi Arabia	73 (medium)	$13,330	N/A	95-100				71.9
Serbia & Montenegro	N/A	$2,200 (2002 est)*	30%*	N/A	10,000 PHAs* (2001 est)			73.97 (2003 est)*
Seychelles	36 (high)	$17,030	N/A	80-94	N/A			71.25 (2003 est)*

Country	Human Development Index (HDI) Ranking	GDP per capita (PPP US$)	Population below poverty line	Population with sustainable access to affordable "essential drugs" (percentage range, WHO est.)	People living with HIV/AIDS (% age 15-49), 2001	Malaria cases (per 100,000 people), 2000	Tuberculosis cases (per 100,000 people), 2001	Life expectancy at birth (in years)
Syria	110 (medium)	$3,280	15 – 25%*	80-94				71.5
Tajikistan	113 (medium)	$1,170	60% (2001 est)*	0-49				68.3
Thailand	74 (medium)	$6,400	32.5% on less than $2/day	95-100	1.79%	130	100	68.9
Timor-Leste (East Timor)	N/A	$500* (2001 est)	42% (2002 est)*	N/A				65.2*
Tonga	N/A	$2,200* (2001 est)	N/A	N/A	N/A			68.88 (2003 est)*
Turkmenistan	87 (medium)	$4,320	34.4% (2001est)*	50-79				66.6
Ukraine	75 (medium)	$4,350	25% on less than $4/day	50-79				69.2
United States	7 (high)	$34,320	N/A	95-100	0.61%	--	2	76.9
Uzbekistan	101 (medium)	$2,460	N/A	50-79				69.3
Venezuela	69 (medium)	$5,670	32% on less than $2/day	80-94	0.5%	94	22	73.5
Viet Nam	109 (medium)	$2,070	63.7% on less than $2/day	80-94				68.6