24 January 2007

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

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Dear Mr. Clark & Ms. Zirger:

Re: Submission for review of "Canada's Access to Medicines Regime"

We write in response to the Consultation Paper released in November 2006 as part of the government's review of what is now described as "Canada's Access to Medicines Regime" (CAMR),[1] the legislative scheme under the *Patent Act* and the *Food and Drugs Act* to enable compulsory licensing of patented pharmaceuticals for the purpose of exporting less expensive products to eligible developing countries to address public health problems. We take this opportunity to provide you with our views regarding necessary reforms to the regime that was created by Parliament's unanimous enactment in May 2004 of the *Jean Chrétien Pledge to Africa* (JCPA),[2] which was based on the WTO General Council Decision of 30 August 2003[3] and which came into force in May 2005.

A. Mischaracterization of the scope of the CAMR and 2003 WTO Decision

Before outlining our substantive concerns and recommendations, we wish to note a preliminary concern with the way in which the Government of Canada continues to describe both the legislative regime enacted by the *JCPA* and the underlying 2003 WTO General Council Decision. The introduction to the Consultation Paper indicates that the objective of the government's review is to solicit comments as to how the CAMR "can better deliver on Canada's commitment to improve access to less expensive medicines that are urgently needed to treat HIV/AIDS, malaria, tuberculosis, and other epidemics in developing and least-developed countries." The background section of the Consultation Paper states that the "stated purpose" of the 2003 WTO Decision is "to facilitate developing and least-developed countries' access to less expensive medicines needed to treat HIV/AIDS, tuberculosis, malaria and other epidemics."

We note, as we have on previous occasions over the past several years, that the WTO General Council Decision on which the *JCPA* is based is not restricted to dealing with just these three diseases and "other epidemics". This was a point of particular contention in the negotiations that led to the final text of that Decision. The Decision clearly states, in paragraph

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1(a), that it applies to any pharmaceutical product "needed to address the public health problems as recognized in paragraph 1 of the Declaration [on the TRIPS Agreement and Public Health]". Paragraph 1 of that Declaration (the "Doha Declaration") states that WTO Members "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." The text of these WTO documents, and the acrimonious debate between WTO Members over whether a mechanism for enabling compulsory licensing of pharmaceuticals for export should be restricted to addressing only specific diseases or conditions or only products for use in addressing epidemics or emergency situations, make it clear that there is no such limitation in WTO law. The reference to epidemics and to specific diseases is for emphasis only, acknowledging that these public health problems are of particular concern to WTO Members.

Notwithstanding this international consensus, during the drafting of the *JCPA*, the Canadian government again proposed to limit Canada's implementation of the WTO Decision with such restrictions. However, this proposal was again rejected and, as enacted, Canada's law does not contain such a restriction. The stated purpose of the regime is to "facilitate[e] 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" (*Patent Act*, s. 21.01). This formulation, as with that found in the WTO source documents, clearly identifies that the three mentioned diseases and "other epidemics" are public health problems of special concern, but do not constitute an exhaustive list of the problems that may be addressed through use of the Canadian regime.

Given the context of past efforts to narrow the scope of any mechanism for using compulsory licensing for export, we are concerned that the Government of Canada continues to mischaracterize both the WTO Decision and its own legislative regime in a manner that suggests both are limited in this fashion. We urge again that, in any description of the CAMR, the Government of Canada refrain from suggesting that the regime is limited to addressing only specific diseases or situations such as "epidemics" or "emergencies".

B. "Balancing competing policy objectives": flawed premise leads to flawed outcome

By way of further context, we note that the background section of the Consultation Paper indicates that, in drafting the *JCPA*, the Government of Canada was required to advance the humanitarian objectives of the 2003 WTO Decision

> while balancing a number of competing policy objectives, namely:
> - complying with other relevant obligations under TRIPS and the North American Free Trade Agreement (NAFTA);
> - respecting the rights and interests of divergent stakeholders groups; and
> - maintaining the integrity of the domestic patent regime.

With respect, we suggest that herein lies part of the reason why the legislation ultimately enacted has failed to date in delivering on the humanitarian pledge of the regime.

In the process of drafting the *JCPA*, and in its final form, the stated objective of the regime has been compromised by the Government's eagerness to "balance" interests — including balancing the life and health of patients in developing countries against the private commercial interests of patent-holding pharmaceutical companies, who are not ultimately the intended users of the regime and whose economic interest is served by having a regime that ultimately is unused. However, the regime's intended beneficiaries are poor people in countries with limited resources. In order for the regime to deliver on its promise, it must be used by pharmaceutical manufacturers able and willing to produce generic products in Canada for export at lower prices (i.e., generic producers), and by purchasers importing those products into eligible developing countries (whether the governments of such countries or humanitarian non-governmental organizations delivering health care to patients). These are the interests that need to be considered in crafting a legislative scheme that will deliver on the pledge of facilitating access to less expensive medicines and other pharmaceutical products needed by people in developing countries. To the best of our knowledge, at no time during the drafting of the legislation did the Government of Canada consult with experts on intellectual property policy and drug procurement working within developing country governments. To the extent that the needs of patients in developing countries informed the development of Canada's legislation, these perspectives were represented indirectly by Canadian civil society organizations with direct experience "in the field" or working in partnership with civil society organizations in developing countries with relevant expertise.

The other two considerations that are noted should not be overstated. Canada's obligations under NAFTA with respect to intellectual property are the same as those under TRIPS — indeed, the wording is essentially identical, since NAFTA's provisions on intellectual property were the basis for the same provisions in TRIPS. Technically the two sets of obligations are distinct, as they are found in distinct treaties, and hence it was advisable to obtain a specific supplementary agreement with, in particular, the U.S. that it would not rely upon the provisions of NAFTA to impede Canada's implementation of the WTO decision waiving the identical restrictions on compulsory licensing found in TRIPS.[4] But NAFTA did not, and does not, impose upon Canada any obligations with respect to intellectual property rules that are substantively different from those under TRIPS — meaning that NAFTA did not require the addition of any extra features in Canada's legislative regime, nor do NAFTA provisions necessarily preclude the adoption of the recommendations for reform that we present below, which in some cases would require Canada to adopt certain interpretations of "flexibilities" found in TRIPS in order to make CAMR a simpler, more straightforward regime with a greater likelihood of delivering on its stated humanitarian objective. Notwithstanding that NAFTA is a separate treaty regime from TRIPS, it does not present a legal barrier to fundamental reform of CAMR so much as a political challenge — the question is whether the Government of Canada has the courage of its stated conviction, unanimously affirmed by Parliament in 2004, that it wishes its legislative regime on compulsory licensing for export to lead to greater access to medicines needed by patients in many developing countries.

In addition, at no stage in the process was there any proposal put forward that in any way compromised the "integrity of the domestic patent regime", as neither the 2003 WTO Decision nor the *JCPA* ever contemplated anything other than limiting patentees' exclusive patent rights exclusively for the purpose of exporting products from Canada to eligible developing countries,

with no impact on the benefits derived from the Canadian market by patentees as a result of their exclusive patent rights. The measures aimed at preventing diversion of products exported from Canada under compulsory licence, referenced in the WTO Decision, were more than adequate to address this concern — a concern that has often been exaggerated beyond warrant, given the lack of evidence that such diversion represents a significant problem. Implementing the WTO Decision in Canadian law did not require any further "balancing" between achieving the humanitarian objective of greater access to less expensive medicines and protecting the domestic patent regime in Canada.

On the question of "balancing competing policy objectives", we note that the Government makes repeated reference in the Consultation Paper to its international trade obligations and further states that meeting the CAMR's humanitarian objectives cannot be allowed to "undermine intellectual property rights necessary for continued innovation in Canada". Given that the CAMR is aimed at enabling compulsory licensing in Canada solely for the purpose of export to countries that, in their totality, represent but a small fraction of global pharmaceutical sales and profits, while preserving the exclusive marketing monopolies of patentees in the high-income markets that are relevant in driving their decisions regarding spending on research and development, we suggest that this concern is another that is overstated and is not of any particular relevance in determining the legislative and policy reforms needed to make the CAMR more likely to achieve its humanitarian objectives.

We note, however, that the Government has made no reference, in either the *JCPA* or any of its material describing the policy objectives relevant to Canada's regime, of its obligations under international human rights law. As a Member State of the United Nations, Canada is legally bound by the obligations in the *Charter of the United Nations* to work towards achieving "solutions of international…health…problems" and achieving the universal realization of human rights (Articles 55 and 56). In this regard, we note that the *Universal Declaration of Human Rights* recognizes the right of everyone to a standard of living adequate for his or her health and well-being, including medical care (Article 25). Canada has also ratified the *Constitution of the World Health Organization*, which recognizes that "enjoyment of the highest attainable standard of health" is a "fundamental right". Furthermore, Canada has ratified the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), Article 12 of which states 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.

Canada has voted for several unanimous resolutions of the UN Commission on Human Rights recognizing 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."[5] It is well recognized that rights such as this cannot be fully realized overnight. But it is equally well established, as a matter of international law, that there is a binding legal obligation on all states that have ratified the ICESCR to take positive steps toward eventually achieving these fundamental human rights. This means "a specific and continuing obligation to move as expeditiously as possible toward the full realization" of the right to health, including adopting

"appropriate legislative … and other measures" toward this end.[6] Furthermore, the obligations of State Parties are international in scope: States 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".[7] In 2001, Canada and other UN Member States adopted unanimously adopted a *Declaration of Commitment on HIV/AIDS* in which they promised, among other things, to "make every effort to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS".[8] Canada's binding legal obligation, under international law, to take positive action to realize access to medicine in developing countries, must surely also be a "policy objective" that guides the review and reform of the CAMR.

As noted in the Consultation Paper, despite being in force since May 2005, the CAMR has not yet resulted in the export of any eligible pharmaceutical products to eligible importing countries. As we outline in more detail below, part of the explanation lies in the mechanism itself, as embodied both in the *JCPA* enacted by Parliament in 2004 and in the underlying WTO Decision adopted in 2003 — hence our recommendations for substantial reform of key elements of the existing regime so as to implement a simpler, more straightforward and streamlined mechanism that stands a greater chance of meeting the needs of both generic producers and purchasers in developing countries, the two parties who must use the mechanism if it is to realize its humanitarian objective. But if the task is approached, as before, as an exercise in "balancing" competing interests and policy objectives — including some which are not relevant in the calculus and others that have been afforded much greater weight than warranted — then there is a great risk that yet again Canada will compromise the humanitarian objective of the regime in order to placate those whose commercial interests lie in seeing it remain but a paper promise.

C. Legislative reforms needed to the CAMR

As is recognized in the Consultation Paper, Canada's Access to Medicines Regime is failing to meet its goals. It has not yet, at this writing, resulted in the export of any pharmaceutical products to an eligible importing country, notwithstanding the widespread global need for less expensive medicines and other products. The possible use of Canada's regime is influenced by a variety of larger political and economic factors, including the pressure that developing countries face, and have faced for years, from some high-income countries, in particular the United States, to refrain from taking measures such as compulsory licensing to obtain lower-cost pharmaceuticals. However, the challenge currently facing the Government and the Parliament of Canada is to ensure that Canada's legislative regime is drafted in such a way that is as simple, straightforward and streamlined as possible, being cognizant of this political reality and of the practical realities facing both generic manufacturers and developing countries as the producers and procurers of medicines that could be manufactured under compulsory licence. We submit that, in part, the CAMR has not yet delivered on its promise because it is marred by numerous unnecessary features that make it cumbersome and complicated for would-be purchasers seeking to import medicines into developing countries and for would-be generic producers in Canada, to the point that it effectively deters those who might be interested in using the regime. Below, we present recommendations that would replace the existing mechanism with something similar that is simpler and more direct while still in accord with Canada's

obligations as a WTO Member. We also present recommendations for reform that would eliminate some of the unnecessary and counterproductive features of the current regime.

1. Fundamental change to streamline compulsory licensing mechanism

In August 2003, WTO Members declared that the General Council Decision of 30 August 2003, on which Canada's regime is based, represented the promised "expeditious solution" to the problems faced by countries with insufficient pharmaceutical manufacturing capacity in making effective use of compulsory licensing to obtain less expensive pharmaceuticals to address public health problems. To date, one Canadian generic manufacturer and one would-be purchaser, Médecins Sans Frontières, have attempted to use the CAMR to obtain a lower-cost, generic version of a fixed-dose combination anti-retroviral drug (ARV) to treat people living with HIV/AIDS in a particular country in which MSF operates treatment projects. Those efforts began as far back as May 2004, shortly after the legislation was enacted by Parliament. Yet this experience has illustrated that the mechanism set out in the WTO General Council Decision of 30 August 2003, and enacted in Canada via the *JCPA*, is "neither expeditious, nor a solution".[9]

Canada was the first country to implement a detailed legislative regime for implementing the 2003 WTO Decision. As noted in the Consultation Paper, Norway, India, the European Union, the Netherlands, South Korea, and China have also adopted legislation, regulations or other instruments that in some way, with varying degrees of specificity and restrictiveness, implement the 2003 WTO Decision to permit compulsory licensing of patented pharmaceuticals for export to certain eligible countries. However, there have not yet been any exports under any of these comparable regimes either. More than three years after the WTO decision was adopted, not a single country has yet made the requisite notification to the WTO of its intent to use the mechanism to import generic medicines from another country.[10]

The experience of over three years suggests that there is a fundamental problem with the mechanism set out in the 2003 WTO Decision itself, which mechanism is replicated, with additional elements, in Canada's *JCPA*. While we present further below numerous recommendations addressing specific features of Canada's existing legislative regime that unnecessarily burdensome, in our view a more fundamental reform to Canada's regime of compulsory licensing for export is required, so as to replace the current unwieldy process with a more effective one. We therefore urge the Government to not just limit the current review exercise to solely making some adjustments, important as they are, to the existing regime, but to also go further and fundamentally redesign the basic process for granting legal authorization to produce generic pharmaceuticals for export to eligible countries.

The 2003 WTO Decision embodied in Canada's law ignores the realities of both generic drug manufacturers and developing countries. Developing countries need simple contract processes that will ensure sustainable supplies of essential medicines or other pharmaceutical products; these contracts must be flexible enough to adjust to changing needs. The WTO decision as enacted by Canada, however, forces generic companies through unnecessary red tape to get a licence to manufacture and export each patented drug, and even then allows for export only in a pre-negotiated quantity and to a single country, for at most two years. What is needed

is for Canada to streamline the legal process so that developing countries and generic drug companies can and will use it.

Generic manufacturers should be able to begin the process by easily obtaining, at the outset, a compulsory licence to manufacture and export any patented medicine, not just those on the limited list attached to the original legislation. Generic manufacturers should be able to obtain such authorization without any particular country or specific quantity of the product pre-determined. Such legal authorization could be done via a standing statutory "compulsory licence" – that is, a specific section of the *Patent Act* could be enacted that statutorily authorizes the generic production of any patented pharmaceutical product solely for purposes of export to any eligible country specified in the legislation. Alternatively, if the legislation were to require a specific application for a compulsory licence on a particular product, instead of requiring a generic manufacturer to apply for a separate licence to satisfy every separate order of a drug, the law could grant that manufacturer an initial compulsory licence on a drug as of right. The licence would authorize the company to export that drug to any eligible country specified in the legislation. In either case, whether granted by statutory provision or in the form of a specific licence, certain standard conditions of the authorization, such as the obligation to pay royalties to the patent owner(s) according to the formula found in the current legislation, would be mandated by statute.

With such an authorization in hand, a generic company would be able to negotiate multiple purchasing contracts with multiple developing countries — not just one-off agreements on a country-by-country, order-by-order basis for which a separate licence must then be obtained each time, as is currently the case. The economies of scale that could be achieved could be considerable, contributing to the goal of incentivizing generics to participate and to lowering further the ultimate price developing countries could negotiate with the generic manufacturer.

Since the authorization would already have been obtained at the outset of the process, there would be no need for a period of negotiation over the terms of a voluntary licence between generic manufacturers and brand-name patentees. Generic producers would still be required to pay royalties to the patent holders based on the contracts they do end up signing with purchasers; by law, the generic producer would be required to disclose basic details about the value of those contracts and pay the applicable royalties on a regular basis to the patent owners. The existing law already contains a sensible formula that calculates the royalty payable on any given contract based on the UN Human Development Index ranking of the importing country.

By granting a compulsory licence at the outset that is not specific to any one country, and instead including a standard licence condition that legally obliges the generic manufacturer to pay royalties in accordance with this clearly defined formula, based on whatever contracts may end up being negotiated, there is no obligation for an interested developing country purchaser to first step forward and risk retaliation — for example, from the United States or other country opposed to the use of compulsory licensing — all for the uncertain reward of delivery of one medicine in a predetermined quantity for a limited period of time. In addition, countries would not be faced with the unrealistic task of predicting exactly the quantity of the drug that will be needed in a given time period; adjustments in the quantity produced and purchased could fluctuate over time depending on the health needs of the country in question. Such a process

would give generic manufacturers and developing countries much more incentive to make use of the law and realize the goal of getting medicines to people who need them in developing countries.

Would such an alternative mechanism be permissible under WTO rules? Clearly it departs in some important ways from the 2003 WTO Decision that has unfortunately proved to be flawed. But the 2003 WTO Decision is not the only option open to WTO Members. The Decision states expressly:

> This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the [Doha] Declaration, and to their interpretation.[11]

It is, therefore, time to return to the question of TRIPS Article 30 as the basis for solving the problem, as was originally proposed by a number of developing countries and a range of NGOs active in efforts to secure access to medicines in the developing world, with the support of the WHO.[12] Article 30 states:

Exceptions to Rights Conferred

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

As is evident, this provision is worded in very open-ended fashion, and affords important leeway to WTO Members in implementing their other TRIPS obligations regarding granting exclusive patent rights. Furthermore, TRIPS Article 1(1) expressly states that WTO "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." In the 2001 Doha Declaration, WTO Members unanimously agreed that TRIPS should be interpreted and implemented so as to promote access to medicines and reaffirmed "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose" (para. 4).

Canada has implemented the mechanism negotiated at the WTO in August 2003. So far, Canada's model has not worked — but neither has the 2003 WTO Decision yet worked at all in any country where implemented. As the first country to implement the WTO Decision with a complete legislative framework, and the jurisdiction in which the most concerted efforts have been made to date to use the mechanism, Canada is in a position to set a positive global precedent by acknowledging that the 2003 WTO Decision does not in fact address the needs of developing countries, and to implement instead a better model, within the bounds of WTO rules, that stands a greater likelihood of actually engaging generic producers and developing country purchasers in increasing access to more affordable treatment for millions. Canada has the clear legal right to use the flexibility that it retains under TRIPS Article 30 to legislate, as a set of "limited exceptions" to exclusive patent rights, the simpler, streamlined mechanism for compulsory licensing for export that has been described above. It also has an ethical duty to take

such action, and similarly a legal obligation under international human rights treaties it has ratified that oblige it to take steps, individually and through international assistance and cooperation, to prevent, treat and control epidemic and other diseases as part of achieving fully the right of everyone to the highest attainable standard of health.

> **Recommendation: Provide authorizations to export which are not limited to a single drug-order for a single country. This can be done by creating a standing statutory authorization in the *Patent Act* authorizing the manufacture of generic version of any drug patented in Canada for export to any eligible country specific in the legislation. Alternatively, under CAMR, a manufacturer could be granted a single, open-ended licence on a given drug that authorizes of that drug to any eligible country specified in the legislation. Through either mechanism, the authorization would not be limited to a pre-determined quantity of the product, but would require periodic remittance to the patentee(s) of royalties payable according to the existing formula in the CAMR.**

2. Eligible importers

(a) NGOs as purchasers/importers of Canadian-made generics

Under Canada's current law, an NGO providing humanitarian relief in an eligible developing country has to get the "permission" of that country's government to import under CAMR. (This is in addition to the existing, sensible requirement that the medicine be approved for use by the importing country's drug regulatory authority.) Requiring this extra permission for NGOs to do their jobs is not required by any WTO rules, and creates an additional, unnecessary barrier to patients getting the medicines they need. As long as the medicine satisfies the conditions established by the drug regulatory authority in the importing country, there is no reason why a non-governmental purchaser of Canadian-made generics importing those products into an eligible country should require the "permission" of the importing country's government in order to purchase its supplies from this source. This additional hurdle is easily eliminated and should be.

> **Recommendation: Canada should eliminate the requirement that NGOs get the 'permission' of the importing country government.**

(b) Classification and treatment of non-WTO developing countries

Under the current legislation, a developing country that is neither a WTO Member nor an LDC can procure cheaper medicines from Canadian generic producers only if:

- it is eligible for "official development assistance" according to the Organization for Economic Cooperation and Development (OECD);[13]
- it declares a "national emergency or other circumstances of extreme urgency"; *and*

- it specifies the name and quantity of a specific product needed for dealing with that emergency.[14]

This approach creates an indefensible double standard between developing countries that belong to the WTO and those that do not. During the negotiations that ultimately led to the 2003 WTO Decision, efforts to limit sovereign developing countries to using compulsory licensing to import medicines only in "emergency" situations were rejected, and in the end the decision contains no such restriction (except in the case of middle-income and transitional countries that agreed to limit their use of the system as importers in this way). It should also be remembered that the 2001 Doha Declaration explicitly reaffirmed that WTO Members are free to determine for themselves the grounds upon which to use compulsory licensing.

In addition to the three criteria noted above, if any non-WTO developing country (including an LDC) wishes in the future to be added to the relevant schedule of countries under the *Patent Act*, it must state that it undertakes to adopt the measures set out in the WTO Decision (paragraph 4) aimed at preventing diversion of the product — even though it is not bound by WTO rules.[15] Furthermore, a pre-condition to being eligible is that the importing country agrees the imported product "will not be used for commercial purposes".[16] This condition is <u>not</u> required by the language of the WTO General Council Chairperson's Statement made in conjunction with the adoption of the 2003 WTO Decision — namely, the "shared understanding" of WTO Members that the system set out in the WTO decision "should be used in good faith to protect public health and… not be an instrument to pursue industrial or commercial policy objectives".[17] Under the *JCPA*, an importing country may be struck off the list of those eligible to import from a Canadian generic supplier if it permits such use.[18] Yet the term "commercial purposes" is undefined in Canada's legislation. As has been noted previously:

> This provision is clearly aimed at limiting the possibility of commercial competition in the importing country's marketplace, hindering the longer-term benefit that competition could have in reducing medicine prices. It also raises questions about the distribution of imported generics via the private sector (e.g., pharmacists) in the importing country. Will this be considered a "commercial purpose"? If so, such a provision fails to recognize the reality that many people in developing countries, as elsewhere, need to turn to private pharmacies when purchasing medicines, which are also frequently paid for out of their own pocket rather than covered by a public scheme. This provision is unnecessary under TRIPS and the WTO Decision; it should not have been included in the Canadian legislation, nor should this approach be replicated by other jurisdictions.[19]

These additional hurdles are not required of WTO member countries under WTO rules; it is an indefensible double standard to require them of non-WTO developing countries. Patients' access to more affordable medicines should not depend on whether their country belongs to the WTO.

Finally, we note that in the event that a (non-LDC), non-WTO developing country is found to be eligible to import Canadian-made generics under CAMR, that country is added to Schedule 4 of the *Patent Act*. This is inappropriate. Schedule 4 is the list of higher-income WTO Members that have already stated they will not use the mechanism set out in the 2003 WTO Decision as importers except in cases of national emergency. Schedule 3 is the list of

developing countries that are WTO Members; this is the list on which non-WTO developing countries should be added, in the interests of equivalence.

> **Recommendation: Eliminate the provisions in the current law that require a non-LDC, non-WTO developing country to declare a national emergency or similar circumstance, and to specify in advance the name and quantity of a particular drug, in order to become an eligible importer of generic pharmaceuticals produced under compulsory licence in Canada.**
>
> **Recommendation: Eliminate the requirement to promise that the imported product will not be used for "commercial purposes", as this may unnecessarily limit distribution of the product within the importing country through private channels.**
>
> **Recommendation: Repeal the corresponding provisions that enable a country to be struck off the list of eligible importing countries for not satisfying these conditions.**
>
> **Recommendation: Non-WTO developing countries who are determined to be eligible for addition as importing countries should not be added to Schedule 4 of the *Patent Act,* but to the existing list of developing countries set out in Schedule 3.**

(c) Regional trade groups

As noted in the Consultation Paper, under the 2003 WTO Decision, in the case that a developing or least-developed country WTO Member is party to a regional trade agreement with other countries, at least half of whom are least-developed countries, it is permitted for that country, having imported pharmaceutical products under a compulsory licence, to re-export those products to the other developing or least-developed country members of that regional trade group. At the moment, there is uncertainty under Canada's current legislative regime as to whether the CAMR would permit export from Canada, under compulsory licence, of generic pharmaceutical products to an eligible country from which re-exportation to other countries in an eligible regional trade group would or might occur, in accordance with the 2003 WTO Decision. In particular, *Patent Act* s. 21.14(g) could be interpreted as permitting the termination of the generic manufacturer's authorization in such a circumstance, on the basis that "the product was exported, other than in the normal course of transit, to a country or WTO Member other than the country or WTO Member named in the authorization." In addition, there may be uncertainty, under the current provisions of the CAMR, as to the applicable royalty rate in such a circumstance. In cases where it is known in advance that such re-exportation is planned, as part of a regional pooling between different purchasing countries in that regional trade group, such uncertainties could be resolved satisfactorily through the good faith of the patentee(s) and the licence-holder, or by specifying a particular condition in the compulsory licence itself. However, this may not be a realistic expectation.

Recommendation: The CAMR should be amended to enable, without confusion, the use of compulsory licensing to supply, under a simple process and with a single licence, a number of developing countries within a regional trade group as contemplated by the 2003 WTO Decision.

3. Eligible pharmaceutical products

(a) List of eligible drugs in Schedule 1

As noted above, in the lengthy and divisive negotiations that ultimately led to the 2003 WTO Decision, several high-income Members pushed for various restrictions on the scope of any mechanism facilitating compulsory licensing for export — including attempts to limit it to only specific pharmaceutical products.[20] These efforts were roundly condemned by civil society activists as unethical and unsound health policy, and firmly rejected by developing countries. Ultimately, all WTO Members agreed that there would be no such limitations. As noted above, the WTO decision states simply that the mechanism in the decision applies in the case of a "pharmaceutical product", which is defined as follows:

> "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

The list of products subject to compulsory licensing, set out in Schedule 1 to the *Patent Act*, represents a step back from the international consensus achieved with the 2003 WTO Decision. By introducing a limited list of products in its implementing legislation, Canada, which had repeatedly indicated it would wait for a multilateral solution to be agreed at the WTO, has unilaterally undermined that consensus. Furthermore, the legislation creates an unnecessarily complicated bureaucratic process for expanding the list — a Cabinet decision following a recommendation from each of the Ministers of Health and Industry. As we asked in 2004, before the House of Commons Standing Committee on Industry, Science and Technology during hearings into the *JCPA*, why is Canada's Cabinet the gatekeeper for developing countries' access to less costly medicines through the use of policy tools such as compulsory licensing?[21]

The Consultation Paper asks whether Schedule 1 is necessary to avoid delays due to litigation. Yet this question is misguided. As long as the definition of "pharmaceutical product" is clear, there would be little basis on which a patentee could challenge the issuing of an authorization to a generic manufacturer to produce such a product for export. In fact, the experience to date with Schedule 1 has been that it creates an added hurdle to the use of the CAMR, rather than easing its use and avoiding delay. We have previously expressed the concern that the process envisioned for adding products to Schedule 1 would create further delay, as well as multiple opportunities for patent-holding pharmaceutical companies to lobby successfully to block any addition.

In the days leading up to the final vote on the *JCPA* in the House of Commons, these concerns proved well-founded. Members of the Standing Committee discussed adding several medicines to the list annexed to the bill. One Standing Committee member, the Industry critic for the New Democratic Party (NDP), proposed adding the drugs moxifloxacin and clarithromycin, both of which are used to treat pneumonia, a condition of particular significance to people with compromised immune systems. Clarithromycin is also used prophylactically to prevent mycobacterium avium complex (MAC), a life-threatening infection in people living with HIV/AIDS. A version of clarithromycin produced by an Indian generic manufacturer is among the HIV/AIDS medicines pre-qualified by the World Health Organization as meeting the WHO's quality standards. At the Standing Committee, all parties agreed that, absent any technical objections by Health Canada to a particular drug, these medicines would be added to the bill by motion when it came before the House of Commons for final reading and adoption. Health Canada indicated that it had no objection to the addition of either moxifloxacin or clarithromycin to Schedule 1.

Yet the MP who had put forward these additions subsequently received calls from Bayer, the pharmaceutical company that holds the Canadian patent on the drug moxifloxacin, objecting to its inclusion on Schedule 1, and at least one pharmaceutical company also contacted Ministers' offices objecting to the addition of any medicines to the list.[22] Following pressure from the pharmaceutical industry, a Minister's office subsequently contacted the MP to request that he withdraw some of his motions to add specific drugs — products that all parties had already agreed would be added. Subsequently, during the consideration of these motions on the floor of the House of Commons, MPs from other parties argued against the addition of these medicines to the list of products covered by its bill. Government representatives stated during the Parliamentary debate that moxifloxacin and clarithromycin were not on the WHO Model List of Essential Medicines, and claimed (incorrectly) that these medicines were not needed to treat HIV/AIDS, TB or malaria.[23] This was in direct contradiction to assurances that government officials had made repeatedly to NGOs, namely that including a list of specific products in the bill would not be used to limit the scope of the legislation to just products on the WHO Model List or to medicines for treating people living with HIV/AIDS, TB or malaria, given that the 2003 WTO Decision does not, by international consensus, contain such restrictions.

This experience illustrates the pitfalls of having such a list of products. Since the passage of the legislation, the list in Schedule 1 has been amended twice in response to requests from generic manufacturers and NGOs: in September 2005 to add a fixed-dose combination AIDS drug containing the antiretrovirals zidovudine (AZT), lamivudine (3TC) and nevirapine (NVP),[24] and again in September 2006 to add the anti-influenza antiviral oseltamivir (marketed by the patentee under the brand-name Tamiflu).[25] In each case, what had been repeatedly represented as being a simple process in fact took months before the government acted, and only following repeated urging by NGOs and would-be manufacturers. Judging from the experience with the Canadian legislation, any such mechanism for limiting the scope of compulsory licensing legislation to specific pharmaceutical products — which is not only unnecessary under the 2003 WTO Decision, but also contrary to its very spirit — should be avoided.

Recommendation: Schedule 1 should be deleted in its entirety. As an alternative, a simple amendment would be to add to the existing Schedule 1

the entry "any other patented product of the pharmaceutical sector". The definitions of "pharmaceutical product" and "patented product" in the *Patent Act*, for the purposes of CAMR, need to be worded as clearly and inclusively as possible, so as to avoid any misinterpretation that would provide a basis for litigation by a patentee seeking to block use of the regime to produce a pharmaceutical product for export under compulsory licence.

(b) Active pharmaceutical ingredients and other technologies

We have recommended above that Schedule 1 be deleted in its entirety. If this amendment were made, obviously the question of adding active pharmaceutical ingredients (APIs) to the schedule would be moot. However, in support of achieving its stated humanitarian objective, the CAMR should facilitate the export of APIs. Similarly, other patented technologies may be necessary to use medicines effectively (e.g., various testing technologies needed to confirm HIV infection or to monitor the effects of treatment with anti-retroviral or other medicines). The 2003 WTO Decision defines "pharmaceutical product" as meaning "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems" of developing countries, expressly including "active ingredients necessary for its manufacture and diagnostic kits needed for its use" (para. 1(a)).

If interpreted correctly, the relevant definitions currently found in the *Patent Act* (s. 21.02) mean that the CAMR does extend to include both APIs and other products. The definition of "pharmaceutical product" for the purposes of the CAMR includes "any patented product listed in Schedule 1", and the language of this definition and that of "patented product" does not impose any limitation that would exclude APIs or other health technologies from being listed on Schedule 1. However, to avoid any confusion, it would be advisable for the legislation to make clear that these products are covered under the definition of "pharmaceutical product".

Recommendation: Enact amendments explicitly clarifying that active pharmaceutical ingredients and other patented products (e.g., test kits) are included within the definition of "pharmaceutical products" that are eligible for compulsory licensing for export under CAMR.

4. Health Canada's drug review

We are pleased to note that Health Canada has reached an understanding with the World Health Organization whereby the WHO will accept the results of Health Canada's review of pharmaceutical products produced under CAMR for the purposes of the WHO Prequalification Project. This is a positive development and such an arrangement should certainly be maintained, in the interests of speeding the procurement and delivery in future of medicines manufactured under the CAMR. However, while maintaining such an arrangement, we note that requiring Health Canada approval of a generic manufacturer's product before granting a compulsory licence for export is an additional requirement not mandated by the 2003 WTO Decision. Nor

do other drugs require Health Canada approval for export; this requirement is mandated by law only for drugs produced under compulsory licence.

Since many developing countries will require WHO pre-qualification of the generic product in question before purchasing it, requiring Health Canada approval of the generic manufacturer's product as an absolute precondition before the manufacturer can get a licence to manufacture for export can lead to duplication of effort and add unnecessary delay. Some countries may also wish to have their own drug regulatory authority approve the product, although this is likely to be a minority of developing countries that might use the CAMR to obtain lower-cost generic products, given the costs associated with maintaining such a regulatory capacity. Other importing countries may be content to accept the approval granted by a drug regulatory authority in certain countries with recognized standards of review. It should be within the purview of the importing country, and not the Government of Canada, to determine the regulatory review process on which it wishes to base procurement decisions. The CAMR should be amended to reflect this variety of processes that can be relied upon by the importing country to assess the safety, efficacy and quality of products being imported.

> **Recommendation: For purposes of granting a compulsory licence authorizing production for export, Canada should at least accept either Health Canada approval *or* WHO pre-qualification of the product as sufficient. Alternatively, the CAMR could be reformed further to accept approval by the importing country's own drug regulatory authority, or by a regulatory authority satisfactory to the importing country, as sufficient for granting a compulsory licence.**

5. Application process for a compulsory licence

We have recommended above some fundamental changes to the existing regime that would put in its place a more direct, simple and streamlined approach for granting the legal authorization to produce generic versions of patented pharmaceutical products for export to eligible countries, without pre-determined quantities destined for specific countries. We have submitted that such a revised process is in accord with Canada's obligations as a WTO Member, as it makes use of flexibilities under TRIPS Article 30 that the 2003 WTO Decision and other WTO legal instruments clearly state are open to Canada to interpret and implement as it sees fit in its domestic legal system.

However, to the extent that CAMR continues to be modelled on the 2003 WTO Decision and the underlying provisions of TRIPS Article 31, it is imperative to more clearly define and limit the requirement, pursuant to Article 31(b), that efforts first be made to negotiate a voluntary licence with the patentee before a compulsory licence may be issued. These negotiations involve high costs and considerable delays, and create a disincentive for use of the system, which should be minimized to the greatest extent possible.

Canada's legislation should provide clear limits on the negotiations required. At the moment, a period of at least 30 days is specified; there is no need, however, for such a lengthy

period of time, given the parameters and limits already imposed by statute on the use of the system, including the formula specifying what a reasonable royalty rate would be in the event a compulsory licence is issued. Patentees should not need such an extended period of time to decide whether to agree to the request for a voluntary licence. As we have recommended previously, a period of 15 days should be more than sufficient.

In addition, we note here a particular example of how the legislation creating the CAMR could be amended to reflect the political and economic reality faced by developing countries that might seek to use such a regime to import lower-cost medicines to address public health problems. Under s. 21.04 of the *Patent Act* as it currently stands, the Commissioner of Patents may not issue a compulsory licence unless the applicant has provided to the patentee(s), for a period of at least 30 days, not only the name and quantity of the pharmaceutical product to be exported but also "the name of the country or WTO Member to which the pharmaceutical product is to be exported". As a result, for at least a month, before there is even any assurance for the would-be purchasing country that the Canadian generic supplier is able legally to supply the product for which a tentative agreement has been reached, the importing country is exposed to almost certain pressure from the patented pharmaceutical industry and powerful countries such as the United States or other like-minded WTO Members to refrain from proceeding with the use of compulsory licensing to secure needed medicines. Recent history provides numerous examples of such pressure, extending even to threats of serious trade sanctions and other retaliation, notwithstanding that such conduct runs counter to the letter and spirit not only of agreements reached at the WTO (such as the 2003 Decision that underlies CAMR) but also those states' obligations under international human rights law to not impede access to medicines.

This is one factor that has almost certainly contributed to the fact that no country has yet notified the WTO of its intention to use the 2003 WTO Decision, whether to import Canadian-made generics under CAMR or from other jurisdictions that have implemented similar regimes. It is a further argument for implementing, instead of the current case-by-case, country-by-country process, the alternative approach we have proposed above, based on TRIPS Article 30, that would provide the necessary legal authorization to Canadian generic manufactures without restricting it to a particular contract for a specific quantity of a particular product to a specific, named country. At the very least, this section of the *Patent Act* can be revised such that, even if the existing cumbersome process of applying for a compulsory licence for every specific drug order is maintained, there would be no requirement to disclose the name of the country in question as a precondition of obtaining the compulsory licence. Instead, it could be simply required that the generic manufacturer request a voluntary licence from the patentee(s) on the reasonable condition that the generic manufacturer will disclose the name of the country following receipt of the licence and will pay the applicable royalty rate pursuant to the existing CAMR formula.

Finally, as noted in the Consultation Paper, under TRIPS Article 31(b), the requirement of first attempting to negotiate a voluntary licence may be waived in circumstances of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use of the product in question. Canada's legislation does not currently reflect this, although a number of other jurisdictions have done so in their implementation of the 2003 WTO Decision. In addition, although it is not noted in the Consultation Paper, TRIPS Article 31(k) also provides

that this requirement of prior negotiation may also be waived in cases where compulsory licensing is undertaken "to remedy a practice determined after judicial or administrative process to be anti-competitive". Following WTO rules, where the importing country wants to import the drug to address a national emergency or similar circumstance, or for public non-commercial use, or to remedy anti-competitive practices by patentee(s) in the importing country, there should be no requirement that the generic manufacturer first try to negotiate a voluntary licence before obtaining a compulsory licence.

Recommendation: The time for negotiating a voluntary licence from the patentee(s) should be capped at no more than 15 days.

Recommendation: The *Patent Act* should be amended so as to state explicitly that the requirement to first seek a voluntary licence from the patentee(s) does not apply in the event that the importing country is facing a national emergency or other circumstances of extreme urgency or is importing the product for public non-commercial use, or has authorized the import under compulsory licence as a remedy for practices by the patentee(s) that have been determined by judicial or administrative process in the importing country to be anti-competitive.

Recommendation: The *Patent Act* should be amended so as to not require advance disclosure, before a licence is obtained, of the name of the country to which the product will be exported. Instead, it should simply be required, as a condition of the licence, whether issued voluntarily or compulsorily, that the generic manufacture will pay the applicable royalty as determined by the existing CAMR formula.

6. Duration of the licence

There should be no arbitrary limit on the term of a compulsory licence, limiting the economies of scale needed to make compulsory licensing viable for generic manufacturers and throwing into question for potential developing-country purchasers the long-term sustainability of supplies. The current time-limit of 2 years is arbitrary and not required by the 2003 WTO Decision. This measure constitutes a major barrier to the participation of generic companies, since they must re-initiate the long approval process to continue exporting the product beyond a 2-year period. This also prevents generic companies from guaranteeing to purchasers that they will be able to continue supplying after two years. The current two-year limit should be abolished, and a compulsory licence should run for the remainder of the patent term on the originator product.

If there is a specified term of a licence, extending or renewing the licence should be a simple, largely automatic process. There should be no need to undertake anew the entire process (including attempting to negotiate a voluntary licence with the patentee) simply to continue a relationship with a developing country purchaser beyond the term of the original contract, or to

expand production of the same product to supply new customers, whether in the same or another eligible importing country.

It has been suggested previously that such a limit is needed to preserve flexibility for developing countries. However, this rationale is untenable:

> Such a paternalistic approach, trying to legislate by proxy a limit on the term of a contract, seems strange given the government's general unwillingness to interfere with parties' freedom to bargain in the marketplace. There is little reason to believe that developing countries (or other bulk purchasers of pharmaceuticals) are unable to adequately assess and project their own medicine needs and contract accordingly. Furthermore, such a proposition is irrelevant to the issue of compulsory licensing; should this argument not also be applicable in every situation where a developing country is purchasing medicines from a pharmaceutical supplier, be it a brand-name company or a generic one? The fact that a generic producer may, in respect of a specific drug that is still patented in Canada, need a compulsory licence to manufacture and supply that medicine is a secondary consideration. It seems, rather, that this cap represents a misguided and unnecessary attempt to constrain generic producers' ability to compete effectively in the marketplace, by limiting the term of a compulsory licence available under the legislation.[26]

Recommendation: Section 21.09 of the *Patent Act* should be repealed, and should be replaced with a section that makes clear that, unless revoked on other grounds set out in the legislation, a compulsory licence is valid so long as the product in question remains under patent (or patents) in Canada.

7. "Good faith" clause

Under the current legislative regime (section 21.17 of the *Patent Act*), the patentee(s) may apply to the Federal Court of Canada for an order terminating a compulsory license, or ordering a royalty higher than what is specified by the sliding scale in the regulations under the *Patent Act* on the basis that a generic company's contract with a purchaser is "commercial" in nature. In such an application, the patent owner must allege that the generic producer is charging an average price for the product that exceeds 25 percent of the average price being charged for the patented product in Canada. In determining whether the agreement is "commercial" in nature, the Federal Court must consider: (i) the need for the generic manufacturer holding the compulsory licence to make "a reasonable return sufficient to sustain a continued participation in humanitarian initiatives"; (ii) the ordinarily levels of profitability in Canada of commercial agreements involving pharmaceutical products; and (iii) international trends in prices as reported by the UN for the supply of pharmaceutical products for humanitarian purposes. If the generic producer can demonstrate, through an audit supervised by the Court, that its average price is less than 15 percent above its direct manufacturing costs, the court may not issue such an order.

It has been suggested that these provisions in the *JCPA* seek to control the prices charged by generic producers to developing country purchasers. Indeed, that may well be the objective, as well as the effect. However, the measures adopted in pursuit of this objective are ill-considered, assuming for the sake of argument that they are even necessary given likely

competition in the global marketplace — from either brand-name companies pressured into lowering their prices or, more importantly, from other generic manufacturers, including those in other countries, some of whom likely have lower costs of production on some fronts. The objective of constraining prices charged by generic manufacturers exporting medicines under compulsory licence from Canada could be achieved through other means, such as through conditions imposed in the compulsory licence itself when issued. Instead, the Government chose a far less direct method of achieving its objective, one that places enforcement of this crude price control provision in the hands of patentees, who have not only a long history of vexatious litigation against generics aimed at delaying and undermining marketplace competition, but also an obvious incentive and now a legal basis for such tactics embedded right in the CAMR legislation itself.

It has also been suggested that these provisions to control generic manufacturers' prices reflect the humanitarian, and not commercial, spirit of the 2003 WTO Decision and give effect to Canada's obligation to act in "good faith" to prevent the use of the system agreed in that decision from being used to pursue industrial or commercial policy objectives. However, such a detailed and obvious disincentive to generic producers using the system is in no way required by the WTO Decision or the accompanying Chairperson's statement of the same date, nor by TRIPS itself. The stated commitment in the 2001 Doha Declaration, referred to again in the 2003 WTO Decision, and reaffirmed yet again in the *JCPA*, is to facilitate access to medicines to address public health problems faced by developing countries. Yet the *JCPA* has created further privileges and legal mechanisms for patent owners to interfere with the simple, straightforward use of compulsory licensing to supply generic pharmaceuticals to developing countries.

Recommendation: Eliminate patent-holders' extra litigation rights by repealing the relevant elements of section 21.08 and all of sections 21.14 and 21.17 of the *Patent Act*.

D. Conclusion

When the *Jean Chrétien Pledge to Africa* was enacted in 2004, it passed with the support of every single Senator and Member of Parliament, and every single party represented in Parliament declared their support for legislation that was supposed to help get more affordable medicines to patients in need in developing countries. To date, however, Canada's Access to Medicines Regime has not delivered on the pledge. We submit that the reforms recommended above would significantly increase the likelihood of fulfilling the promise.

We look forward to the opportunity to discuss these proposals with the Government and Members of Parliament.

Sincerely,

Richard Elliott
Deputy Director

[1] Government of Canada, "Canada's Access to Medicines Regime – Consultation Paper", 11 November 2006, online: http://camr-rcam.hc-sc.gc.ca/camr_rcam_consult_e.html.

[2] *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, S.C. 2004, c. 23.

[3] WTO General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Decision of the General Council of 30 August 2003, WTO Doc. IP/C/W/405 ["2003 WTO Decision"].

[4] Letter from R. Zoellick, U.S. Trade Representative to J. Peterson, Canadian Minister of International Trade, 16 July 2004.

[5] *Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria*, CHR Resolutions 2001/31, 2002/32, 2003/29, 2004/26, and 2005/23.

[6] 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, UN Doc. E/C.12/2004/4, online at: http://www.ohchr.org/english/bodies/cescr/comments.htm.

[7] *Ibid*., at para. 38, with reference to ICESCR Article 2.

[8] *Global Crisis, Global Action: Declaration of Commitment on HIV/AIDS*, GA Res. S-26/2, UN GAOR, 26th Spec. Sess. Supp. No. 1, UN Doc. A/RES/S-26/2 (2001), at para. 55.

[9] Médecins Sans Frontières, *Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable – An Illustration Through Canada's Jean Chrétien Pledge to Africa*, August 2006, online: www.accessmed-msf.org/documents/WTOaugustreport.pdf

[10] See the dedicated webpage on the WTO website for such notifications at www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

[11] 2003 WTO Decision, *supra* note 3 at para. 9.

[12] Statement by the representative of the World Health Organization, WTO Council for TRIPS, 17 September 2002. See also: World Health Organization, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Health Economics and Drugs, Essential Drugs and Medicines Series No. 12, WHO/EDM/PAR/2002.3 (June 2002), online via www.who.int; Prof. F.M. Abbott, "Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health", Occasional Paper 9 (Geneva: Quaker United Nations Office, February 2002) at 40-41, online via www.quno.org; H. Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement" (2003) 21 B.U. Int'l L.J. 101- 136.

[13] In the result, five countries have no option to procure medicines from a Canadian generic supplier while those products remain under patent in Canada: Russian Federation, Ukraine, Belarus, Bahamas, and Libya.

[14] *Patent Act*, s. 21.03(1)(d)(ii).

[15] *Ibid*.

[16] *Ibid*.

[17] General Council Chairperson's Statement of 30 August 2003, in WTO General Council, *Minutes of Meeting* (held on 25, 26 and 30 August 2003), WTO Doc. WT/GC/M/82 at 6 (para. 29), online: WTO http://docs-online.wto.org, also www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm [Chairperson's Statement].

[18] *Patent Act*, s. 21.03(3)(d).

[19] R. Elliott, "Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceuticals for export" (2006) 1 International Journal of Intellectual Property Management 94-112 at 105-106.

[20] F.M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" (2005) 99 American Journal of International Law 317-358 (providing a detailed analysis of the negotiations leading to the Decision).

[21] Canadian HIV/AIDS Legal Network, "Global Access to Medicines: Will Canada Meet the Challenge?", Submission to the House of Commons Standing Committee on Industry, Science and Technology, 26 February 2004.

[22] Glen McGregor, "Drug bill lets 'Big Pharma' call the shots: Government yields to pressure from Bayer to keep new drug off list of HIV/AIDS program", *Ottawa Citizen*, 4 May 2004.

[23] For the transcript of House of Commons debates over Bill C-9, see the entry "Patent Act and Food and Drugs Act (amdt.)" in the index to *Hansard*, the record of chamber business, at www.parl.gc.ca/37/3/parlbus/chambus/house/debates/indexE/p-37-3_-e.htm.

[24] *Order Amending Schedule 1 to the Patent Act*, S.O.R./2005-267, online: http://canadagazette.gc.ca/partII/2005/20050921/html/sor276-e.html.

[25] *Order Amending Schedule 1 to the Patent Act (Oseltamivir Phosphate)*, S.O.R./2006-204, online: http://canadagazette.gc.ca/partII/2006/20061004/html/sor204-e.html.

[26] Elliott, *supra* note 19 at 107.