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# HIV/AIDS POLICY & LAW

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## TRIPS from Doha to Cancún . . . to Ottawa: global developments in access to treatment and Canada's Bill C-56

In November 2003, Canada introduced legislation to amend the Patent Act so that manufacturers could obtain licences to make generic versions of patented pharmaceutical products for export to countries lacking sufficient capacity to produce their own. Bill C-56 aims to implement an August 2003 decision of the World Trade Organization (WTO) that relaxes its rules on pharmaceutical patents to allow this kind of measure. While the bill is a welcome development, it contains several serious flaws that will undermine the initiative and render it largely meaningless. Civil society organizations, including the Canadian HIV/AIDS Legal Network, have called on the Canadian government to remedy the flaws before Bill C-56 is enacted. This article provides an overview of recent global developments leading up to Canada's initiative, as well as an analysis of Bill C-56 itself.

### Access to medicines and the World Trade Organization

#### 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.<sup>1</sup> The Doha Declaration, as it came to be known, was made in response to criticisms from numerous developing countries and from civil society

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organizations to the effect that WTO rules on intellectual property – specifically 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<sup>2</sup> (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.

In the lead-up to the Ministerial Conference, and during the negotiations in Doha, critics pointed out that TRIPS was being interpreted and applied in a manner aimed at deterring governments from pursuing policies to decrease the price of medicines. The hypocrisy of developed countries at the WTO was starkly revealed by events following the terrorist attacks in the United States in September 2001. Five deaths from anthrax distributed through the mail caused concern about future bioterrorism and access to adequate supplies of ciprofloxacin, an antibiotic used to treat the disease. Both Canada and the US threatened to override Bayer's patent rights on the drug unless it supplied the desired quantities at a

reduced price. Yet developing countries such as South Africa and Brazil had been chastised for contemplating similar policies to deal with their HIV/AIDS epidemics and told that they were unacceptably undermining patent rights.<sup>3</sup>

The incident highlighted the double standard at play and fuelled developing countries' demands going into the Doha conference. The declaration that was eventually adopted is politically important because it bolsters efforts to balance protection of private patent rights with the public interest in affordable health care. The Doha Declaration is also significant because, under international law, it must guide future legal interpretations of TRIPS.<sup>4</sup>

Significantly, in the Doha Declaration, 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."<sup>5</sup> It is important to note that the three named diseases and other epidemics are identified as particularly serious illustrations of "public health problems." Contrary to suggestions by some countries and pharmaceutical companies after the Doha conference, the Declaration is *not* limited to covering only these particular problems.

In the Doha Declaration, WTO members also stated that:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to

protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that 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.<sup>6</sup>

WTO members further recognized that this flexibility includes the right of each country "to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."<sup>7</sup> A compulsory licence is an authorization granted to someone

Because it introduces competition into the market, a compulsory licence is one tool for bringing down the price of pharmaceutical products.

other than the patent owner, without the patent owner's consent, to use, make, sell, or import a patented product. Without this licence, a generic pharmaceutical company making its version of a patented product could be sued for patent infringement. TRIPS

requires that when a compulsory licence is issued, the patent owner is entitled to “adequate remuneration” (to be defined under a country’s own laws).<sup>8</sup> Because it introduces competition into the market, a compulsory licence is one tool for bringing down the price of patented medicines and other pharmaceutical products.

### **Limits on exports of generic pharmaceuticals: the Doha paragraph 6 problem**

However, 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. This is the case with most developing countries. Compulsory licences could, however, still be used to authorize imports of generic pharmaceuticals made elsewhere. But, under TRIPS, 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.<sup>9</sup> This limits the possibility of generic pharmaceutical makers in one country getting compulsory licences authorizing them to produce cheaper products for export to other countries in need.

Having recognized the problem – which became known as the “Doha paragraph 6 problem” – WTO members committed to finding “an expeditious solution” by the end of 2002.

Unfortunately, they were unable to meet this deadline.

### **From Doha to Cancún: negotiations on the Doha paragraph 6 problem**

Over the course of the negotiations that followed the Doha Declaration, several countries – including Canada, the European Community (EC) countries, Japan, Australia, and Switzerland – joined with the US in trying to narrow the scope of any “solution.” They sought to impose various conditions and restrictions that were at odds with the text and spirit of the Declaration, such as limiting which countries would be able to use it, and for which diseases, as well as imposing onerous obligations on any attempts to invoke it.<sup>10</sup> Those efforts were resisted by activists and by developing countries, with mixed results (as described below).

### **Developed countries reject simple solution to problem**

In addition to opposing these efforts to narrow the solution, non-governmental organizations (NGOs) also criticized the basic approach being pursued by the US, Canada, and other developed countries, which required a complicated reworking of Article 31 of TRIPS that would introduce unnecessary complexity into any solution, thereby hindering its possible usefulness. Instead, activists proposed that WTO members use the flexibility already found in another article to address the problem.

TRIPS Article 30 says that countries may create, in their own laws, “limited exceptions” to exclusive patent rights, as long as those 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.” NGOs argued that WTO members should agree on an interpretation of Article 30 that would permit, as permissible exceptions to patent rights, all acts associated with producing a patented product that addresses health needs in another country where the product is either not patented or, if it is patented, a compulsory licence has been granted or government use has been made of that patent in accordance with the laws of that country. The NGOs argued that this would be the simplest, easiest way to allow for speedy and effective use of compulsory licensing by countries needing to import cheaper medicines.<sup>11</sup>

The World Health Organization (WHO) also supported this approach.

As negotiations over the text of a solution dragged on, developed countries continued to propose various restrictions.

It released a paper setting out the features of a solution “which are desirable from a public health perspective,” including broad coverage in terms of health problems and the range of medicines, simple and speedy legal procedures in the exporting and importing countries, and equality of opportunities for countries in need of medicines.<sup>12</sup> Based on this analysis, the WHO presented a statement to the WTO Council for TRIPS stating that

the basic public health principle is clear: the people of a country which does not have the capacity for domes-

tic 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.

Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export patented medicines and other health technologies to address public health needs.<sup>13</sup>

However, in the negotiations that followed, the Article 30 approach was dismissed summarily by the US and some other developed countries. Although the EC had initially flirted with the approach, it also eventually favoured a solution based on Article 31. The idea of using Article 30 to solve the problem was eventually abandoned by WTO members, and attention focused on the details of a solution based on modifications to Article 31.<sup>14</sup>

### **US, EC, and other developed countries push for narrow solution**

As negotiations over the text of a solution dragged on into late 2002, developed countries continued to propose various restrictions. For example, Japan opposed the inclusion of vaccines in any solution. The US objected to a draft text that expressly said that the reference to “public health problems” in the Doha Declaration meant more than just HIV/AIDS, tuberculosis, malaria, and other epidemics. The US and the EC pushed for lists that would limit which countries could import generic pharmaceu-

tics, and also sought to limit the system so that only a handful of developing countries could be exporters of generic pharmaceuticals (thereby excluding the possibility of drawing upon the generic-drug-manufacturing capability in the developed world).

By December 2002, all WTO members except the US had approved a draft text of a solution. The US was unwilling to approve the text without the addition of a limited list of diseases for which compulsory licences could be used by developing countries to secure cheaper medicines. As one critic put it: “The US wants to have a global debate over the issue of the scope of disease. [The US President and Trade Representative] want to argue that the diseases their own children receive treatment for are off limits to poor children in poor countries. They cannot win this argument.”<sup>15</sup>

Because of the US position, the WTO negotiations collapsed on 20 December 2002, with no solution reached by the WTO’s own deadline. Further proposals were advanced in 2003 that perpetuated the double standard for developing countries. For example, in February 2003, the TRIPS Council Chairperson proposed to restrict the use of compulsory licensing for many developing countries to “national emergencies or other circumstances of extreme urgency.” Activists pointed out that under TRIPS, wealthy countries are not required to declare the existence of an emergency to make use of compulsory licensing, so it would be unacceptable to require this of developing countries. Furthermore, it would be unsound public health policy to wait until a situation had become an “emergency” before being able to use compulsory licensing to import cheaper medicines.

With no resolution in sight, attention began to turn to the upcoming Fifth WTO Ministerial Conference, in September 2003 in Cancún, Mexico.

### **Solving the Doha paragraph 6 problem: the WTO decision of 30 August 2003**

Finally, less than two weeks before the Cancún conference was to begin, the US agreed to join the consensus previously reached by all other WTO members in December 2002. On 30 August 2003, the General Council of the WTO unanimously adopted a decision on “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.”<sup>16</sup>

The decision is supposed to solve the difficulties faced by WTO members lacking sufficient pharmaceutical manufacturing capacity “in making effective use of compulsory licensing under the TRIPS Agreement.” The decision takes the form of an “interim waiver” of TRIPS Article 31(f), the provision that restricts the use of compulsory licences to produce generic pharmaceuticals for export.

### **Chairperson’s statement: effort to narrow the August 30<sup>th</sup> decision**

However, in the eight months following the breakdown of negotiations in December 2002, the US had succeeded in some of its efforts to narrow the scope of the August 30<sup>th</sup> decision. With the Cancún meeting approaching, the US turned its effort to obtaining a statement from the Chairperson of the General Council setting out WTO members’ “shared understandings” of the August 30<sup>th</sup> decision. A “Chairperson’s statement” was eventually adopted in conjunction with the text of the actual Council decision.<sup>17</sup> The precise legal significance of such a statement remains unclear, although



under international law it would likely be of relevance in interpreting TRIPS and the text of the August 30<sup>th</sup> decision. The US tried to use the Chairperson's statement to attach imitations to the text of the actual decision.

#### Non-commercial motivation

For example, the US unsuccessfully pushed for a statement that the decision would not be used for "commercial gain" – an obvious attempt to limit the system to only government or public production of pharmaceuticals on charitable grounds, and to exclude any possibility of compulsory licences being granted to private generic companies. This proposal was rejected on the grounds that it would severely hamper the system's real effect, given that no private company would produce without the prospect of some commercial gain. In the end, the Chairperson's statement says that the system will "not be an instrument to pursue industrial or commercial policy objectives." It remains to be seen whether the US will use this "understanding" to undermine efforts at increasing the capacity of private, for-profit generic companies to manufacture products for export to importing countries using the new WTO system.

#### Eligible importing WTO members

The US and the EC also sought to establish lists of which countries would be eligible to use the system to import generic pharmaceuticals, based on data about the extent of their manufacturing capacity or level of income. These efforts were also rejected: the decision is clear that WTO members determine for themselves whether to use the system to import pharmaceuticals.

In the case of "least-developed" countries, as defined by the United Nations, the decision deems them automatically to have insufficient pharmaceutical manufacturing capacity and therefore to be eligible to use the scheme in the August 30<sup>th</sup> decision to import generic pharmaceuticals. In the case of any other country belonging to the WTO, it must establish that its capacity is either non-existent or currently insufficient to

The governments of some countries agreed to further restrictions on their sovereign rights to use compulsory licensing in order to placate the pharmaceutical industry and the US government.

meet its needs. However, the Chairperson's statement requires that the country notify the TRIPS Council in writing of how it reached this determination. It also says that any country can raise an issue regarding the interpretation or implementation of the decision for review at the TRIPS Council "with a view to taking appropriate action." This is *not* a requirement that the WTO approve the country's decision. However, this provision could be used by countries such as the US to pressure developing countries not to use the system to import generic pharmaceuticals.

Although it failed to establish a closed list of eligible and ineligible importing countries, the US was successful in getting specific WTO members to commit, on the record,

not to use the system as importers. According to the Chairperson's statement, 11 middle-income countries agreed to use compulsory licences to import pharmaceuticals only in situations of "national emergency or other circumstances of extreme urgency."<sup>18</sup> In addition, 10 Eastern European countries also committed to use compulsory licensing to import in emergency situations only, and to opt out of importing entirely once they join the European Union.<sup>19</sup> Finally, 23 high-income countries committed to opt out of the system entirely, even if confronted with a national emergency for which their own domestic capacity to produce generic medicines is insufficient.<sup>20</sup> The governments of these countries have effectively agreed to further restrictions on their sovereign rights to use compulsory licensing – recognized in TRIPS and reaffirmed in the Doha Declaration – in order to placate the patent-protected pharmaceutical industry and the US government.

#### Reaction to the August 30<sup>th</sup> decision

The August 30<sup>th</sup> decision and accompanying Chairperson's statement received a mixed reaction. The WHO said it was "encouraged" by the decision, but stressed 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.... Given the urgency of the health needs in the poorest countries, the work to implement this agreement must proceed as quickly as possible. The full impact of the agreement will depend on how effectively it can be implemented in countries. 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. WHO continues to urge Member States to consider using to the full the TRIPS flexibilities with regard to the protection of public health.<sup>21</sup>

A coalition of NGOs, including those most directly engaged in the WTO negotiations, issued a statement saying that although the deal was being described as a gift to the poor, it was “a gift bound in red tape.”<sup>22</sup> They were critical of the unnecessary complexity of the system set out in the decision – such as requiring compulsory licences in both importing and exporting countries, and giving the WTO itself new authority to second-guess the decisions of sovereign countries to grant individual compulsory licences – and of other opportunities for the US and other wealthy countries to pressure developing countries into not issuing licences. However, like the WHO, they also urged every country to begin to use the TRIPS flexibilities and the August 30<sup>th</sup> decision to increase access to affordable medicines.

### **Implementing the August 30th decision: Canada’s Bill C-56**

Since the adoption of the Doha Declaration in November 2001, Canadian advocates<sup>23</sup> had been urging the Canadian government to make the necessary legislative changes to allow Canadian generic pharmaceutical manufacturers to supply developing countries. Like other NGOs active at the WTO, they argued that Canada should take advantage of the flexibility offered in TRIPS Article 30 to carve out “limit-

ed exceptions” to patent rights to allow generic exports.

The response had consistently been that action was unlikely until there was an outcome to the multilateral negotiations at the WTO on the Doha paragraph 6 issue. As men-

**NGOs said that although the deal was being described as a gift to the poor, it was “a gift bound in red tape.”**

tioned above, the use of TRIPS Article 30 was not pursued in the WTO negotiations, where discussion focused instead on waiving and/or amending TRIPS Article 31(f).

### **Renewed demand for patent law amendments**

With the adoption of the WTO August 30<sup>th</sup> decision, advocates in Canada redoubled their efforts to get the Canadian government to act.

On 10 September 2003, the Canadian Generic Pharmaceutical Association (CGPA) wrote to the Honourable Pierre Pettigrew, then Minister for International Trade, requesting that the government change its patent laws to allow for the manufacture of generic versions of patented medicines for export.<sup>24</sup> In Cancún at the WTO Ministerial Conference, a representative of Oxfam Canada supported the request, saying it was “one concrete way” Canada could make affordable medicines available to countries in need.<sup>25</sup>

On 12 September 2003, the UN Special Envoy on HIV/AIDS in

Africa, Stephen Lewis, delivered a keynote address at the Annual General Meeting of the Canadian HIV/AIDS Legal Network in Montréal, in which he urged the government to amend the Patent Act immediately, as a step toward realizing the right to health of poor people in developing countries.<sup>26</sup> He reiterated the call a week later, on 20 September 2003, in Nairobi at the International Conference on AIDS and STDs in Africa, where his remarks were more widely reported.

On 23 September 2003, an opinion piece by the Canadian HIV/AIDS Legal Network in the *Globe and Mail*, Canada’s leading national newspaper, declared that “there are no excuses left” and demanded an amendment to the Patent Act.<sup>27</sup> The same day, four national NGOs reiterated the request in a letter to Allan Rock, then Minister of Industry, and other government ministers.<sup>28</sup>

### **Government announcement and reaction**

On 25 September 2003, the government of Canada responded by announcing that it would amend Canadian patent law to implement the WTO decision.<sup>29</sup> The announcement received international attention. UNICEF welcomed the move, saying that it represented “the first major move by a major, industrialised country to overcome a key structural hurdle in getting life-saving medicines to people who desperately need them.”<sup>30</sup>

In contrast, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), the international lobby group for the patented pharmaceutical industry, declared that Stephen Lewis “is leading us all down the

primrose path to a dead end,” and said that Canada’s initiative “won’t solve a thing” and would be a “negative black eye for Canada” that will “very well affect the investment climate.”<sup>31</sup> Harvey Bale, the IFPMA Director-General, suggested that it was more important to increase

The government of Canada’s announcement that it would amend Canadian patent law to implement the WTO decision received international attention.

financial contributions to improve health-care infrastructure in developing countries (a request that Canadian activists had consistently made in conjunction with their request to amend patent laws).

Canadian civil society organizations welcomed the government’s announcement.<sup>32</sup> But, concerned by certain remarks made by government ministers when announcing the planned amendment, they also called on the government not to restrict the amendment to specific diseases or emergencies. They pointed out that such an approach would represent a step backward from the consensus reflected in the August 30<sup>th</sup> decision, which does not impose such limitations.<sup>33</sup>

A few days after the government’s announcement, Médecins Sans Frontières Canada, the Canadian HIV/AIDS Legal Network, Oxfam Canada, and the Canadian Auto Workers union held a joint press conference at which they were joined by Stephen Lewis. Speakers reiterated

their support for the government initiative and urged it to act quickly. They said that the government must not backtrack on the WTO decision by unilaterally re-introducing restrictions such as those on the scope of health problems covered.<sup>34</sup> At the press conference, the Legal Network released a backgrounder, subsequently distributed to all Members of Parliament, making the case for an amendment to the Patent Act that fully reflects the scope of the August 30<sup>th</sup> decision.<sup>35</sup>

In conjunction with the press conference, over 70 NGOs from numerous countries (including China, Germany, Colombia, South Africa, the United Kingdom, Canada, Kenya, Thailand, the US, Nigeria, and Italy) signed a joint NGO statement supporting the initiative but calling on the government of Canada to ensure it did not compromise in fully implementing the August 30<sup>th</sup> decision.<sup>36</sup> The Treatment Action Campaign and the AIDS Law Project of South Africa also issued a joint statement.<sup>37</sup> The message from activists outside Canada was delivered to reporters at the press conference being held in Toronto.

The same day, the media reported that Paul Martin, a few months before assuming the office of Prime Minister, had expressed his support for the initiative.<sup>38</sup> Canada’s Research-Based Pharmaceutical Companies (R<sub>x</sub>&D), the lobby group for Canadian companies producing patented pharmaceuticals, issued a news release saying it would “continue to work with the federal government to frame any legislative proposal to assist in humanitarian relief” but that it could not “comment further until a government decision is taken.” The R<sub>x</sub>&D release also stated that the August 30<sup>th</sup> decision

“relates to the provision of generic medicines to treat HIV/AIDS and other life-threatening diseases such as tuberculosis and malaria.”<sup>39</sup> The Canadian HIV/AIDS Legal Network criticized this statement as a misleadingly narrow characterization of the WTO decision.

### Ongoing advocacy and consultation

Following the government’s announcement, a handful of Canadian civil society organizations engaged in extensive discussions with government officials from five departments, with the objective of ensuring that the government fully implemented the WTO decision, in all its flexibility.

However, by mid October, concern was growing among NGOs that the government had made no public commitment to reflect the full scope of the Doha Declaration and the August 30<sup>th</sup> decision in the amendment, and no commitment to refrain from restricting the amendment to specific diseases or to emergency situations. On 16 October 2003, the media reported that indeed it was the government’s intention to impose these sorts of restrictions.<sup>40</sup> The same day, five organizations issued a joint open letter to the ministers of Industry and of International Trade, asking the government to publicly state its position on five key questions, including these restrictions.<sup>41</sup> The letter was circulated to the media, to other NGOs and to key parliamentarians, and was posted on the web along with other key documents on the campaign for a patent law amendment.

Additional initiatives followed soon after. Over 20 Canadian civil society organizations and over 100 individual Canadians signed a state-

ment urging the Canadian government to quickly amend the Patent Act and not to compromise its initiative by limiting it to specific diseases or to countries facing emergencies.<sup>42</sup> In short order, similar statements were signed by over 100 physicians, health professionals, and medical students in Canada and internationally.<sup>43</sup>

In the House of Commons, Members of Parliament from the New

News reports kept the issue before the public and opinion pieces continued to pressure the government to introduce sound legislation.

Democratic Party repeatedly demanded that the government move quickly to table legislation and not to limit it to specific diseases.<sup>44</sup> News reports<sup>45</sup> kept the issue before the public and opinion pieces<sup>46</sup> continued to pressure the government to introduce sound legislation. Activists from various countries contacted the government, including through its diplomatic representatives abroad, to demand that it not impose unnecessary and unjustified restrictions on the amendment.<sup>47</sup>

Activists also demanded that the US not use intellectual property rules under the North American Free Trade Agreement (NAFTA) to block Canada's initiative – particularly since those rules are identical in key respects to the provisions in TRIPS that had just been addressed, by consensus, in the August 30<sup>th</sup> decision.<sup>48</sup> On 7 October 2003, following a meeting in Montréal of trade ministers from the three NAFTA countries, the US Trade Representative and the

Mexican economy minister stated that they would not oppose the initiative.<sup>49</sup> Some uncertainty about the US position remained; a “senior Canadian official” was reported as saying that it “was understood” that “in keeping with the WTO deal, [exports] would be for treating only AIDS, tuberculosis, malaria and other public health emergencies.”<sup>50</sup> However, activists decided to take the US statement at face value as an agreement not to use NAFTA to block a full implementation by Canada of the August 30<sup>th</sup> decision.

### **Bill C-56: legislation tabled, but flawed**

After further meetings with patented and generic pharmaceutical companies and with NGOs, the government introduced Bill C-56 in the House of Commons on 6 November 2003.<sup>51</sup> The bill proposes to amend the Patent Act to provide for the issuance of compulsory licences allowing generic pharmaceutical manufacturers to make generic versions of patented pharmaceuticals for export to countries that lack their own manufacturing capacity and that use the WTO August 30<sup>th</sup> system to import generics. (The bill does not affect patent holders' monopolies in the Canadian market.)

### **Introduction of legislation welcomed**

With this bill, Canada became the first country to take steps to implement the August 30<sup>th</sup> decision. Bill C-56 was welcomed by the WHO, which said that: “If replicated in other exporting countries, such a decision, coupled with increased efforts to improve global health infrastructure and service delivery could be a major step in closing the treatment gap for millions of people who cannot afford the essential medicines they need.”<sup>52</sup> The

UN Special Rapporteur on the right to health also welcomed the initiative, noting that governments have a responsibility under international human rights law to provide international assistance and cooperation in realizing human rights. He urged that any legislative and policy amendments fully reflect the spirit and scope of the Doha Declaration, along with concurrent obligations under human rights law.<sup>53</sup>

Canadian civil society organizations also applauded the introduction of the legislation. They welcomed the fact that Bill C-56 does not contain any restricted list of diseases or health conditions for which compulsory licensing may be used to obtain pharmaceuticals, and the fact that the bill does not limit the use of compulsory licences to supplying countries facing an emergency or other circumstances of extreme urgency.

In addition, the organizations welcomed the fact that Bill C-56 specifies a low royalty rate of “two percent of the value of the pharmaceutical products exported under the authorization.”<sup>54</sup> This reflects the fact that the ultimate objective is to make it possible for generic manufacturers, likely to be operating on small profit margins on contracts with developing countries, to supply products that are ultimately priced very cheaply for those countries.

### **Flaws in Bill C-56**

However, several serious concerns remain about the legislation. Canadian civil society organizations strongly support the objective of allowing compulsory licensing for exporting lower-cost generic pharmaceutical products to countries in need. But the flaws in Bill C-56, as it is currently drafted, will undermine this objective. Therefore, the legislation needs to be



changed in several key respects before it is enacted, and civil society organizations have called upon the government to “fix the bill.”<sup>55</sup> Four key flaws are discussed below.<sup>56</sup>

**(1) Provisions permitting anti-competitive action by patent holders to block licences for generic manufacturers**

As introduced in Parliament, Bill C-56 creates an unnecessary and undesirable opportunity for Canadian patent holders to engage in anti-competitive action to block generic manufacturers from obtaining licences to produce and export pharmaceuticals. Bill C-56 sets out a process whereby a generic manufacturer wishing to produce a patent-protected product for export must notify the Commissioner of Patents of its intent to apply for a compulsory licence. The notice must set out the name of the product, the quantity to be produced, the country to which it is to be exported, and the terms and conditions of the contract between the generic manufacturer and the government of the country in question.

The notice must also include either a declaration that the product is not patented in the destination country or, if it is patented there, a written statement from the country that it has granted or intends to grant a compulsory licence in accordance with Article 31 of TRIPS. If the importing country belongs to the WTO, the document submitted must be the written notice that the country has provided to the TRIPS Council, in accordance with the August 30<sup>th</sup> decision. The notice must then be sent to the holder of the Canadian patent for the product, and the patent holder then has 30 days to decide how to respond. One of the options open to the patent holder is to voluntarily give the generic man-

ufacturer a licence to make the product for export as set out in the notice it has filed, in exchange for the two-percent royalty set by the bill.<sup>57</sup>

However, under Bill C-56, the patent holder is also given another choice, one not required by TRIPS. The patent holder is granted the right to take over contracts negotiated by generic pharmaceutical manufacturers with developing-country governments.<sup>58</sup> In order to do so, the patent-holding company must meet the terms of the contract negotiated by the generic manufacturer with the developing-country purchaser. Under this scenario, then, not only does the patent holder get to assume the would-be competitor’s contract, but also (a) the patent holder has no obligation to negotiate the terms of a voluntary licence for the generic manufacturer, and (b) the Commissioner of Patents is prevented from issuing a compulsory licence to the generic company. The result is that no licence, either voluntary or compulsory, is obtained by the generic manufacturer.

Initially, in a few cases, this process could secure a lower price on a particular medicine for a developing country that has negotiated a contract with a generic manufacturer. However, generic manufacturers would quickly lose any incentive to negotiate such contracts in the first place. The company holding the patent would be able to repeatedly block the generic manufacturer from obtaining the licence needed to make the product and fulfil the contract. In short order, there would be no potential competition from generic manufacturers and there would be no reason for the brand-name company holding the patent to lower its prices. As the association representing Canada’s generic drug industry pointed out, “if generic pharmaceutical

manufacturers spend time and money arranging the details of an agreement only to have the brand company that holds the patent take over that agreement, they will quickly realize the futility of trying to make the agreement work.”<sup>59</sup>

Furthermore, under Bill C-56, a generic manufacturer could obtain a licence for a maximum of two years.<sup>60</sup> This will likely operate as a further disincentive to generic manufacturers, as they will be unable to supply the pharmaceuticals for a significant period of time and achieve the economies of scale necessary to keep prices low but still make a small profit. Furthermore, it means that the company owning the Canadian patent will have another opportunity, after only two years, to “scoop” a contract from a generic manufacturer and block a new licence. This might be a particularly attractive move for the patent-owning company in a case where the generic manufacturer’s initial contract, perhaps in conjunction with an increase in a country’s funds for purchasing medicines, has led to an increased market for the product.

These provisions in Bill C-56 will frustrate the stated objective of implementing the August 30<sup>th</sup> decision. That decision is aimed at enabling countries lacking pharmaceutical manufacturing capacity to make effective use of compulsory licensing to obtain less expensive pharmaceutical products. Giving Canadian patent holders another means of blocking generic companies from getting licences runs directly counter to this objective. As well, these provisions go beyond what Canada is required to do under TRIPS.

Under Article 31(b) of TRIPS, before a compulsory licence is issued there must first be an effort to negotiate a voluntary licence with the patent

holder on “reasonable commercial terms and conditions.”<sup>61</sup> If those negotiations do not succeed “within a reasonable period of time,” a compulsory licence may be issued by the appropriate authority, which then fixes the “adequate remuneration” to be paid to the patent holder. Either way, however, the generic producer may obtain a licence and the patent holder receives some compensation.

Currently, Canada’s Bill C-56 would create an added benefit for patent holders: by taking over a contract negotiated by a generic manufacturer, the patent holder can block the generic manufacturer from obtaining any licence at all, whether voluntary or compulsory. In this way, the bill goes beyond Canada’s obligations under TRIPS to protect intellectual property rights, to the detriment of efforts to respond to public health problems in developing countries.

## **(2) Limited list of pharmaceutical products**

Bill C-56 also includes a limited list of pharmaceutical products for which a compulsory licence may be obtained.<sup>62</sup> The list consists of those products on the WHO Model List of Essential Medicines that are patented in Canada (as of the date of Bill C-56’s introduction in the House of Commons). Bill C-56 also states that the Cabinet of the government of Canada may authorize the addition (or removal) of any other “patented product that may be used to address public health problems,” and that the Cabinet may establish an “advisory committee” to advise it on products to be added to (or removed from) the approved list.<sup>63</sup>

The list in Bill C-56 is flawed because it contains a very limited number of products. For example, eight of the antiretroviral drugs

(ARVs) used to treat HIV/AIDS currently approved for sale, and patented, in Canada are not included on the list of products for which a compulsory licence may be obtained. Nor are combination formulations such as Trizivir and Combivir. Both products contain the drug lamivudine (3TC), which is one of the most commonly prescribed ARVs, but is not included in Bill C-56.

Formulations of several drugs in a single pill, with a simpler dosing regimen, can be of particular benefit in settings where support systems and health-care infrastructure are less than ideal, a factor to be considered in scaling up access to ARVs in many parts of the developing world. As part of its recently launched “3 by 5” initiative, which aims to get ARV treatment to three million people living with HIV/AIDS in the developing world by 2005, the WHO has added three generic versions of fixed-dose combinations for first-line treatment to its list of medicines meeting WHO standards of quality, safety, and efficacy.<sup>64</sup> Two of the drugs in those combinations – lamivudine and nevirapine – are not covered by the list found in Bill C-56.

Civil society organizations have questioned the need for any list. A limited list of products would represent a step backward from the August 30<sup>th</sup> decision, in which all WTO members endorsed an approach that is not restricted to specific medicines or other products. Furthermore, requiring approval by Canada’s Cabinet for the addition of a product to the list puts the Canadian government in the position of gatekeeper over developing countries’ access to lower-cost Canadian generic pharmaceuticals, and introduces further delay. In addition, having a political body such as the Cabinet making these determina-

tions opens the door to lobbying by patent holders to prevent a given product from being listed.

**Civil society organizations have put forward proposals to improve aspects of the bill.**

Civil society organizations have therefore put forward proposals to improve this aspect of the bill. The objective is to ensure that the Canadian legislation respects the right of sovereign nations to determine for themselves which problems warrant the use of compulsory licensing to obtain less expensive pharmaceutical products.

## **(3) Denial of benefit to some countries that are not WTO members**

Under the current scheme proposed in Bill C-56, all least-developed countries may benefit from the export of generic pharmaceutical products from Canada, whether or not they belong to the WTO.<sup>65</sup> However, in the case of countries that are not least-developed countries, Bill C-56 only recognizes countries that are WTO members. Countries that do not belong to the WTO are unable to benefit from the possibility of importing generic pharmaceuticals from Canada. This includes several countries facing numerous public health problems – including serious HIV/AIDS epidemics in some cases – with limited

resources, high levels of poverty, and low levels of access to medicines.<sup>66</sup> There is no sound basis for excluding such countries from potentially benefiting under this legislation. A developing country should not have to be a member of the WTO to be able to import lower-cost medicines from Canadian suppliers.

#### (4) No provision for NGOs to procure generic medicines

Currently, Bill C-56 only contemplates that a government, or an “agent of that government,” could enter into a contract with a Canadian generic manufacturer to purchase a pharmaceutical product. NGOs and other private-sector entities providing treatment in a developing country are not “agents” of government, and so may not be covered by the bill. Assurances from government drafters notwithstanding, it would be a stretch to interpret the phrase “agent of that government” as encompassing non-government organizations. Yet NGOs are often an important provider of health care in many developing countries, and in humanitarian crises. It would be unwise to require NGOs to be designated as government agents in order to be able to obtain necessary medical supplies for the patients they treat. It would also introduce further delays and provide another opportunity for governments, particularly if they have poor relations with NGOs, to play politics with the lives and health of people needing treatment.

There is nothing in the August 30<sup>th</sup> decision that limits the use of the system to governments and their agents, nor is this required under TRIPS. This limitation should be removed, and the bill should expressly provide for generic manufacturers contracting directly with NGOs to supply lower-cost pharmaceuticals.

### The future of Bill C-56 and the August 30<sup>th</sup> decision

Bill C-56 was introduced in the House of Commons on 6 November 2003.

The following day was expected to be the last sitting day before that session of Parliament was prorogued (ie, terminated) by outgoing Prime Minister Jean Chrétien, in anticipation of the election of a new leader of the Liberal Party who would also assume the office of Prime Minister. The House Leader of the Liberal Party secured all-party agreement to pass the legislation quickly through all three required readings before prorogation.

However, concerned about the serious flaws in the bill, civil society organizations mobilized on 6 and 7 November and contacted both the governing Liberal Party and other parties in the House of Commons. They urged that the bill not be passed in its current, flawed form, but rather that it be sent to committee for further discussion and debate so that it could be improved.<sup>67</sup> As a result, the government decided to not seek third and final reading of Bill C-56 immediately,<sup>68</sup> a decision supported by the New Democratic Party. Instead, the bill passed through first and second readings, and was sent to the House of Commons Standing Committee on Industry, Science and Technology for further consideration.<sup>69</sup>

When outgoing Prime Minister Chrétien prorogued Parliament on 12 November 2003, Bill C-56 died on the order paper. Two days later, Canadian activists gathered outside the Metro Convention Centre in downtown Toronto where the governing Liberal Party was holding its national convention to confirm the election of Paul Martin as new party leader and as new Prime Minister of Canada. Wearing

costumes and using props, they played a game of “street hockey for global health” to dramatize their demand that Martin fix Bill C-56 and pass it quickly.<sup>70</sup> Activists also distributed leaflets with the message to party delegates inside the Convention Centre, and did media interviews.

At the time of writing, it had been reported that incoming Prime Minister Paul Martin planned to re-introduce the bill in the next session of Parliament in early 2004. Given previous all-party support for the bill, it was anticipated that the bill would be reinstated at the same stage it had reached in the previous session, meaning that the process would resume with Standing Committee hearings. Paul Martin was also reported as having acknowledged that there are “shortcomings” in Bill C-56 as tabled.<sup>71</sup> Canadian activists continue to call on Martin and the government to “fix the bill” and ensure that it is passed quickly in the next session of Parliament.<sup>72</sup>

Advocacy also remains critical at the WTO. The August 30<sup>th</sup> decision states that the Council for TRIPS will, by the end of 2003, start preparing a more permanent amendment to the TRIPS Agreement, to replace the interim waiver, with a view to adopting that amendment by mid-2004. Once an amendment is adopted and takes effect in any given WTO member country, the August 30<sup>th</sup> decision, and any waivers it grants, will end for that country.<sup>73</sup> NGOs have called for WTO member countries “to draft an amendment to the TRIPS that simplifies and clarifies the procedures and removes unnecessary obstacles to the export of medicines to address public health problems.”<sup>74</sup>

Canadian activists will also need to ensure that the process of securing a more permanent solution at the WTO

will not be used to undermine Bill C-56 and, similarly, that any negative features in Bill C-56 are not used as a bad precedent to argue for a weakened permanent solution at the WTO.

## Conclusion

Beyond amending patent laws to facilitate access to lower-cost pharmaceuticals, many other steps must be taken to mount an effective global response to the HIV/AIDS pandemic and other health challenges – including mobilizing the resources necessary for purchasing pharmaceuticals, strengthening health-care systems where they are currently lacking, and demonstrating strong political leadership to overcome the stigma and discrimination that still undermine HIV prevention efforts and keep people from accessing HIV testing and care, treatment, and support.

But Bill C-56 is an important initiative. It is symbolically important, because a developed country implementing the August 30<sup>th</sup> decision – if it is done correctly and in good faith – helps further bolster the political feasibility of other developing countries also using policy options such as compulsory licensing to secure less expensive pharmaceuticals. And, if it eventually leads to Canadian generic manufacturers supplying products at significantly lower prices than might otherwise be available to patients in developing countries, then it will also be of great practical benefit. It remains to be seen whether the promise will be realized.

– Richard Elliott

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The text of Bill C-56 and additional information and updates about the Canadian patent law amendment can be found at [www.aidslaw.ca](http://www.aidslaw.ca), as can various documents from Canadian NGOs relating to the patent law amendment and other aspects of global access to treatment. Texts of WTO documents can be found via [www.wto.org](http://www.wto.org). Many detailed documents about the WTO negotiations over TRIPS and public health can be found on the website of the Consumer Project Technology at [www.cptech.org](http://www.cptech.org).

<sup>1</sup> Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/2. For a summary and commentary on the Declaration, see R Elliott, WTO Ministerial Conference adopts Declaration on TRIPS and Public Health, *Canadian HIV/AIDS Policy & Law Review* 2002; 6(3): 50-52.

<sup>2</sup> Annex 1C to the Agreement Establishing the World Trade Organization, 14 April 1994.

<sup>3</sup> For a summary of these cases, see: A Kleinsmidt, Pharmaceutical companies abandon case against South Africa: victory for people with HIV/AIDS, *Canadian HIV/AIDS Policy & Law Review* 2001; 6(1/2): 75-76; R Elliott, US files WTO complaints against Brazil over requirement for "local working" of patents, *Canadian HIV/AIDS Policy & Law Review* 2000; 5(4): 28. Many key documents from these cases may be found on the websites of the Treatment Action Campaign ([www.tac.org.za](http://www.tac.org.za)) and the Consumer Project on Technology ([www.cptech.org](http://www.cptech.org)).

<sup>4</sup> Pursuant to Article 31(3) of the 1969 Vienna Convention on the Law of Treaties, any interpretation of the TRIPS Agreement 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. Under WTO law, these Vienna Convention rules for interpreting treaties have been recognized as rules of customary international law as well. This means the rules bind all countries, not just those countries that have ratified the Vienna Convention.

<sup>5</sup> Doha Declaration, supra, note 1 at para 1.

<sup>6</sup> Ibid. at para 4.

<sup>7</sup> Ibid. at para 5(b).

<sup>8</sup> TRIPS, supra, note 2 at Article 31(h).

<sup>9</sup> Ibid. at Article 31(f). Note that this restriction does not apply where a compulsory licence is issued to remedy a practice that a court or administrative process has found to be "anti-competitive": TRIPS Article 31(k).

<sup>10</sup> For a summary of post-Doha negotiations, see R Elliott, WTO: failure to meet deadline on Doha commitments regarding access to generic drugs, *Canadian HIV/AIDS Policy & Law Review* 2003; 8(1): 38-40; and R Elliott, MH Bonin, C Devine, Patents, International Trade Law & Access to Essential Medicines (3<sup>rd</sup> ed), Canadian HIV/AIDS Legal Network & Médecins Sans Frontières Canada, March 2003. See also: Médecins Sans Frontières: Reneging on Doha: an MSF analysis of recent attempts to restrict developing countries' use of compulsory licensing to a set list of diseases, May 2003; and Doha Derailed: A

Progress Report on TRIPS and Access to Medicines – MSF Briefing for the 5<sup>th</sup> WTO Ministerial Conference, Cancún 2003 (available via [www.msf.org](http://www.msf.org)); and Prof. Fred Abbott, Canada and the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Slides from presentation on Parliament Hill, sponsored by North-South Institute, 21 October 2003 (available via [www.aidslaw.ca](http://www.aidslaw.ca)).

<sup>11</sup> Letter to TRIPS Council on Paragraph 6, from Consumer Project on Technology, Médecins Sans Frontières, Oxfam International, Health Gap Coalition, Third World Network and Essential Action, 28 January 2002.

<sup>12</sup> Implications of the Doha Declaration on the TRIPS Agreement and Public Health, Health Economics and Drugs, EDM Series No. 12, WHO/EDM/PAR/2002.3 (June 2002).

<sup>13</sup> Statement by the representative of the World Health Organization, WTO Council for TRIPS, 17 September 2002.

<sup>14</sup> It should be noted, however, that the text of the solution finally adopted in August 2003 expressly says that the decision is "without prejudice to the rights, obligations and flexibilities" that WTO members have under other provisions in the TRIPS Agreement. Therefore it remains legally open for WTO members to experiment with measures under Article 30 that could be used to increase access to affordable pharmaceuticals, including through export – although any WTO member doing so would likely face considerable pressure from one or more of the more powerful developed countries in the WTO.

<sup>15</sup> James Love, Consumer Project on Technology, CPTEch statement on collapse of Doha paragraph 6 negotiations, 20 December 2002.

<sup>16</sup> "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.

<sup>17</sup> General Council Chairperson's statement, 30 August 2003.

<sup>18</sup> Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

<sup>19</sup> Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, and Slovenia.

<sup>20</sup> Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the United States.

<sup>21</sup> Statement of the World Health Organization on WTO access to medicines decision, Geneva, 1 September 2003.

<sup>22</sup> Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines: A "Gift" Bound in Red Tape, 10 September 2003.

<sup>23</sup> Members of the Global Treatment Access Group (GTAG) had repeatedly urged this action by the government. The GTAG is a working group of Canadian civil society organizations undertaking joint efforts to realize the human right to health globally, with a particular focus on access to comprehensive care, treatment, and support for people with HIV/AIDS and other health needs in developing countries. More information about GTAG is available via [www.aidslaw.ca](http://www.aidslaw.ca).

<sup>24</sup> Letter from Canadian Generic Pharmaceutical Association to Hon. Pierre Pettigrew, 10 September 2003; S Chase, Generic drug makers seek export rights, *Globe and Mail*, 11 September 2003: B1, B6; T Cohen, Drug companies ask Canada to change laws, *Associated Press*, 12 September 2003.



- <sup>25</sup> S Chase. Generic drug makers seek export rights. *Globe and Mail*, 11 September 2003: B1, B6.
- <sup>26</sup> CBC National News, CBC Radio, 13 September 2003.
- <sup>27</sup> R Elliott. Canada can carry much more. *Globe and Mail*, 23 September 2003: A23.
- <sup>28</sup> Letter from Canadian HIV/AIDS Legal Network, Médecins Sans Frontières Canada, Oxfam Canada and Interagency Coalition on AIDS and Development to Hon. Allan Rock, 23 September 2003.
- <sup>29</sup> H Scofield, S Chase. Ottawa heeds call on AIDS. *Globe and Mail*, 26 September 2003: A1, A9; D Fagan, H Scofield, S Chase. Ottawa scrambles to meet AIDS-drug pledge: a key initiative shapes up in public view and the government rushes to keep up. *Globe and Mail*, 4 October 2003: A20.
- <sup>30</sup> UNICEF hails Canada's move to expand access to AIDS drugs. Media release, 29 September 2003.
- <sup>31</sup> S Chase, D Fagan. Drug companies balk at Ottawa's plan. *Globe and Mail*, 27 September 2003.
- <sup>32</sup> Eg, National Union of Public and General Employees. AIDS in Africa: good news at last on generic drugs, NUPGE welcomes announcement but wants to see the legislation. Press release, 26 September 2003.
- <sup>33</sup> Canadian HIV/AIDS Legal Network. Press release: Export of generic medicines to developing countries: amendment to Patent Act must benefit as many as possible, urge Canadian organizations, 26 September 2003; Médecins Sans Frontières Canada. Press release: MSF supports federal decision but says it's not enough, 26 September 2003.
- <sup>34</sup> Médecins Sans Frontières Canada & Canadian HIV/AIDS Legal Network. Press release: Save Lives Now: Amend Without Delay – Amending Canada's Patent Act to allow exports of generic medicines, 1 October 2003; H Scofield, P Knox. Big drug companies embrace AIDS plan. *Globe and Mail*, 2 October 2003: A1, A4; Canada to be first G-7 country to allow export of generic HIV/AIDS drugs. *BRIDGES Weekly Trade News Digest* 2003; 7(32): 1 October 2003; A Silversides. "No turning back" on cheap AIDS drugs for poor nations, UN vows. *Canadian Medical Association Journal* 2003; 169(10): 1067 (11 November 2003).
- <sup>35</sup> Canadian HIV/AIDS Legal Network. Protecting Global Health & Human Rights: Why and How the Patent Act Should Be Amended to Allow Generic Drug Exports to Developing Countries. October 2003.
- <sup>36</sup> Joint NGO Statement on Canada's Efforts to Amend the Patent Act to Increase Access to Generic Medicines (October 2003).
- <sup>37</sup> South Africa's Treatment Action Campaign (TAC) and AIDS Law Project (ALP) Welcome Canada's Commitment to Ensuring Access to Medicines, 1 October 2003.
- <sup>38</sup> H Scofield. Martin endorses AIDS plan. *Globe and Mail*, 1 October 2003: A1, A5.
- <sup>39</sup> Canada's Research-Based Pharmaceutical Companies. News release: Partnership for developing countries, 1 October 2003.
- <sup>40</sup> S Chase, H Scofield. Ottawa leans toward limits on cheap-drug distribution. *Globe and Mail*, 16 October 2003: A9.
- <sup>41</sup> Canadian HIV/AIDS Legal Network, MSF Canada, Oxfam Canada, Canadian Labour Congress & Interagency Coalition on AIDS and Development. Amending the Patent Act to Authorize Exports of Generic Medicines to Developing Countries: An Open Letter to the Government of Canada, 16 October 2003.
- <sup>42</sup> Medicines for All: Don't Compromise Health in Amending the Patent Act (October 2003).
- <sup>43</sup> The Need for Affordable Medicines in the Developing World: The Patent Act and Exports of Generic Pharmaceuticals. Statements by Canadian and international physicians, and by Canadian and international health organizations and professionals (October 2003).
- <sup>44</sup> Eg, question by Svend Robinson (Burnaby-Douglas, NDP) to Minister for International Trade, 23 October 2003; question by Bill Blaikie (Winnipeg-Transcona, NDP) to Prime Minister, 28 October 2003.
- <sup>45</sup> Eg, H Scofield. Lewis urges Ottawa to table legislation on AIDS medicine. *Globe and Mail*, 25 October 2003: A5; R Trichur. Africa: Can Canada help save it from AIDS? [Halifax] *Chronicle-Herald*, 30 October 2003: A10.
- <sup>46</sup> Editorial. Canada targets AIDS. *Toronto Star*, 4 October 2003; D Morley. We led on AIDS. Why hang back now? *Globe and Mail*, 24 October 2003: A17; J Dussault. Sauver des millions de vies – La Loi sur les brevets doit être amendée, Le gouvernement du Canada ne doit surtout pas s'arrêter à mi-chemin. *Le Devoir*, 24 October 2003; R Elliott. Canada has an opportunity to show real leadership on "big pharma." *Hill Times*, 27 October 2003.
- <sup>47</sup> Health GAP (Global Access Project) Action Alert. Progress on Access to Affordable Medicines in Jeopardy: Will Canada Give in to Pharmaceutical Industry Pressure?, 20 October 2003.
- <sup>48</sup> Eg, R Weissman, Essential Information. Briefing Note: NAFTA issues in the context of the Canadian implementation of the paragraph 6 agreement, 7 October 2003. See also: H Scofield, S Chase. Canada to seek assent on AIDS drug plan. *Globe and Mail*, 7 October 2003: A11.
- <sup>49</sup> P White. US, Mexico support Canada on generic drug aid. *Reuters*, 7 October; S Chase, H Scofield. Mexico, US back export of cheaper AIDS drugs. *Globe and Mail*, 8 October 2003: A4.
- <sup>50</sup> Chase & Scofield, *ibid*.
- <sup>51</sup> Department of Foreign Affairs and International Trade. News release: Government of Canada introduces legislative changes to enable export of much-needed, lower-cost pharmaceutical products to developing countries; A Dunfield. PM introduces bill to allow cheaper drugs for poor nations. *Globe and Mail*, 6 November 2003; New Democratic Party of Canada. Media release: New Democrats committed to the Lewis legacy, 6 November 2003.
- <sup>52</sup> Statement of the World Health Organization on Canada's proposed legislative changes for medicines, Geneva, 7 November 2003.
- <sup>53</sup> UN Press Release: UN rights expert welcomes Canadian initiative on access to low-cost drugs in developing countries, 7 November 2003.
- <sup>54</sup> Bill C-56, s 21.08.
- <sup>55</sup> Canadian HIV/AIDS Legal Network. Media release: Canada can set global precedent with Patent Act changes, but flaws in legislation could undermine potential benefit, 6 November 2003; Oxfam Canada & Oxfam Québec. Media release: Generic medicines for poor countries – Oxfam urges quick action on patent amendment, calls for changes, 6 November 2003; Canadian Council for International Cooperation. Media release: Canada helps world's poorest and sickest, NGOs congratulate government for access to essential medicines commitment, 6 November 2003; MSF Canada. Media release: Canadian Patent Act Amendment – Medicines for All! Not Yet, 6 November 2003. See also: R Elliott. Flirting with flawed patent law amendment, Canada may undermine welcome "access to medicines" initiative. *BRIDGES Monthly Review*, November 2003, Year 7, No 8, at 21-22 (available at [www.ictsd.org/monthly/bridges/BRIDGES7-8.pdf](http://www.ictsd.org/monthly/bridges/BRIDGES7-8.pdf)).
- <sup>56</sup> See also: Canadian HIV/AIDS Legal Network. Amendment to Canada's Patent Act to authorize export of generic pharmaceuticals: Update – 10 November 2003.
- <sup>57</sup> Bill C-56, s 21.08.
- <sup>58</sup> Bill C-56, ss 21.04(6)(a) and 21.04(7)(a), s 21.05(5).
- <sup>59</sup> CGPA. News release: Generic industry welcomes introduction of access to generic medicines bill, Details of full legal and regulatory package will determine practical effect, 6 November 2003.
- <sup>60</sup> Bill C-56, s 21.09.
- <sup>61</sup> Note that this requirement to first negotiate for a voluntary licence may be waived in cases of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use": TRIPS Article 31 (b).
- <sup>62</sup> Bill C-56, Schedule 1.
- <sup>63</sup> Bill C-56, s 21.03(1)(a).
- <sup>64</sup> World Health Organization. Media release: WHO adds new fixed dose combinations to its list of quality products for AIDS treatment – Key component of 3 by 5 strategy, 1 December 2003.
- <sup>65</sup> The UN recognizes 49 countries as "least-developed countries." Of these, all have been included in Bill C-56, with the exception of Myanmar (a WTO member), which omission arises because of the lack of diplomatic relations between the military dictatorship in that country and Canada. This omission needs to be corrected; patients needing affordable medicines should not be further penalized for the misfortune of living under a dictatorship.
- <sup>66</sup> Some of the excluded countries are Viet Nam, Russian Federation, Belarus, Algeria, Serbia and Montenegro, Kazakhstan, East Timor, Ukraine, Azerbaijan, Uzbekistan, and Tajikistan, among others.
- <sup>67</sup> Canadian HIV/AIDS Legal Network. Media release: Bill C-56 on medicines for developing countries is flawed, House of Commons should amend bill and get it right, 7 November 2003.
- <sup>68</sup> S Chase. Poor-nation drug bill: Liberals table it, but admit it's not ready. *Globe and Mail*, 7 November 2003: A3; Committee to work AIDS bill into shape. *Globe and Mail*, 8 November 2003: A16.
- <sup>69</sup> For a transcript of debates and questions on Bill C-56 in the House of Commons, and information about the status of the bill, see the website of the Parliament of Canada at [www.parl.gc.ca](http://www.parl.gc.ca).
- <sup>70</sup> MSF, Canadian HIV/AIDS Legal Network, World Vision & CAP-AIDS. Media release: Street Hockey for Global Health – Canadian activists dramatize call on new Prime Minister to pass legislation allowing cheaper medicines for developing countries, 14 November 2003.
- <sup>71</sup> S Rubec. Money tight, Martin warns. *London Free Press*, 16 November 2003: 5; S Rubec. Martin set to trim fat, PM-to-be lays out agenda in election-style book. *Toronto Sun*, 16 November 2003: 3; S Rubec. Paul plans tight ship: newly crowned Grit leader pleads fiscal poverty. *Winnipeg Sun*, 16 November 2003: A8.
- <sup>72</sup> Eg, statement from Canadian HIV/AIDS Legal Network in "The Fight Against HIV/AIDS Must Continue," joint media release from seven national Canadian organizations responding to HIV/AIDS to mark World AIDS Day, 29 November 2003.
- <sup>73</sup> Decision of the General Council of 30 August 2003, *supra*, note 16 at para 11.
- <sup>74</sup> Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines, *supra*, note 22.