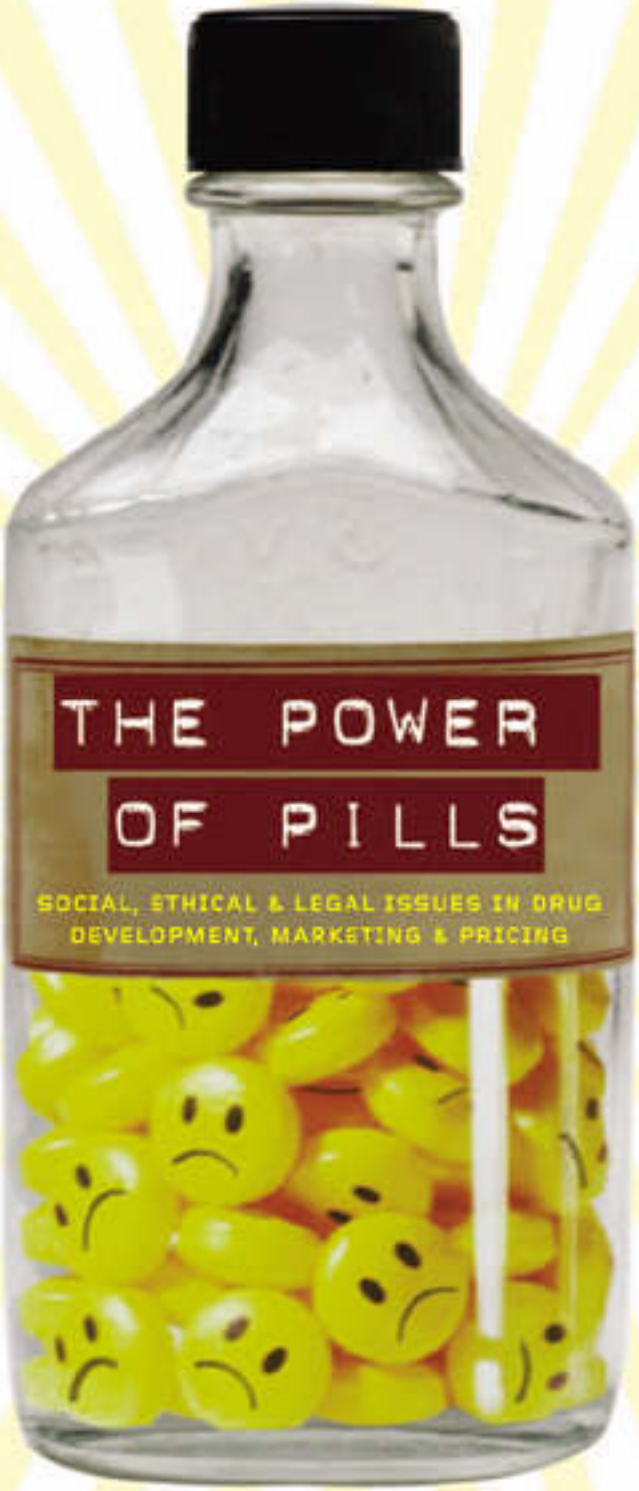


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# 21 Medicines for all? Commitment and compromise in the fight for Canada's law on compulsory licensing for export

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The WTO TRIPS Agreement requires all WTO member countries to adopt certain minimum standards for protecting private IPR, including with respect to pharmaceutical inventions (WTO 1994). Those rules create temporary monopolies over patented pharmaceuticals, meaning the patent holder can charge high(er) prices, a matter of particular concern in developing countries facing HIV/AIDS and other health problems along with widespread poverty and few resources to spend on expensive patented drugs.

Nonetheless, TRIPS (Article 31) also permits "compulsory licensing" – that is, authorizing someone other than the patent holder to use, make, sell, or import a patented product without the patent holder's consent. In exchange, the recipient of the compulsory license must generally pay "adequate remuneration" to the patent holder (to be defined under a WTO member's own laws). By introducing competition from generic manufacturers, compulsory licensing is one policy tool that can bring down prices. A declaration unanimously adopted by WTO members at their Fourth Ministerial Conference in Doha, Qatar in November 2001 reaffirmed that "[e]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted" (WTO 2001, paragraph 5(b)). (It should be noted that, contrary to popular misconception and regularly inaccurate media reports, TRIPS does not limit WTO members to using compulsory licensing only in the event of public health "emergencies" or "crises.")

However, the "Doha Declaration" also recognized 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" (WTO 2001, paragraph 6). TRIPS Article 31(f) says that ordinarily compulsory licensing may only be used "predominantly" for the purpose of supplying the domestic market of the country where the license is issued. (This restriction does not apply where a compulsory license is issued to remedy a practice that a court or administrative process has found to be "anti-competitive" (WTO 1994, Article 31(k)). This limits the use of compulsory licensing to produce generic pharmaceuticals for export. This restriction on exporters means that countries lacking sufficient pharmaceutical manufacturing capacity, and

hence with little or no ability to authorize domestic production of generics, find it difficult to effectively use compulsory licensing to address their population's health needs through importation. WTO members committed to finding "an expeditious solution" to this problem.

On August 30, 2003, after protracted, divisive negotiations, the WTO GC unanimously adopted a decision waiving, on an interim basis, the provision in TRIPS Article 31(f) that says compulsory licensing may only be used "predominantly" to supply the domestic market (WTO 2003). In November 2003, Canada became the first country to introduce legislation implementing the WTO decision; that law passed Parliament in May 2004 and came into force in May 2005. The legislation allows generic drug manufacturers to obtain compulsory licenses on pharmaceutical products still under patent in Canada for the purpose of producing lower-cost, equivalent products for export to eligible countries.

Canadian civil society groups, organized loosely under the aegis of GTAG, not only provided the impetus for the bill but were crucial to securing important amendments before it was enacted in its final form. In some respects, the legislation sets a number of positive precedents. But the government's unprincipled willingness to compromise its initiative to placate the multinational patented pharmaceutical industry means that the legislation falls short of being a model worth simply replicating elsewhere. Rather, activists and organizations working for access to medicines should appreciate both its merits and flaws. To that end, this paper provides an overview of civil society's campaigning for the legislation and assesses the final outcome.

## Steps toward implementing the WTO Decision in Canada: Bill C-56

Canadian activists had been lobbying the government on the issue of TRIPS and access to medicines since early 2001. (For more detailed information, including copies of many of the Canadian NGO documents cited here, see the webpage of CHLN at http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm.) Shortly after the WTO GC's Decision in August 2003 on compulsory licensing of pharmaceuticals for export, Canadian activists redoubled their efforts. In mid-September 2003, after discussions with the CHLN, Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa, former Canadian ambassador to the UN and a highly respected figure with a long history in Canadian public life, publicly urged the government to amend the Patent Act immediately (CBC 2003). An opinion piece in the leading national newspaper by the CHLN declared 'there are no excuses left" and called for an amendment (Elliott 2003). Four national NGOs reiterated the request in a letter to the MoI (CHLN et al. 2003).

Shortly thereafter, the government responded by announcing that it would amend Canadian patent law to implement the WTO Decision (Fagan, Scoffield, and Chase 2003; Scoffield and Chase 2003). Officials from four federal government departments were tasked with drafting the legislation. On November 6, 2003, as one of the last acts of the administration of outgoing PM Jean Chrétien, the government introduced Bill C-56 (PoC 2003) in the HoC for first reading (DFAIT 2003; Dunfield 2003; NDP 2003).

As anticipated, the Bill proposed amendments to the Patent Act; it also included some related amendments to the Food and Drug Act.

Activists welcomed the fact that Bill C-56 did not contain a restricted list of diseases or health conditions for which compulsory licensing may be used to obtain pharmaceuticals, and did not limit the use of compulsory licenses to supplying countries facing an emergency or other circumstance of extreme urgency. Previous reports had revealed the government's original intention to incorporate such restrictions, a move that GTAG members had condemned as a bad faith step back from the consensus reflected in the WTO Decision (CHLN et al. 2003). In addition, they welcomed the fact that Bill C-56 specified a low royalty rate of "two percent of the value of the pharmaceutical products exported under the authorisation"(PoC 2003, section 21.08), reflecting the ultimate objective of making it possible for generic manufacturers, likely to be operating on small profit margins on contracts with developing countries, to supply products that are priced very cheaply.

However, the Bill failed to implement the full flexibility in patent rules that had been agreed at the WTO and included unnecessary privileges to patent-holding pharmaceutical companies undermining the entire initiative. Activists labeled the most egregious of these the "right of first refusal" – a provision that would have allowed the company with the patent on a medicine to block any compulsory license issuing to a generic producer by scooping the contract it had negotiated with a developing country purchaser, as long as the patent-holding company was willing to match the terms negotiated in that contract.

Activists were focused on persuading the government to fix the Bill, to avoid setting a poor "TRIPS-plus" precedent. The next day (November 7, 2003) was to be the last sitting day before the end of the parliamentary session, in anticipation of the election of a new leader of the governing LP, who would also become the new PM. The LP had secured agreement from the three opposition parties that they would support quick passage of the Bill through all three readings before the session ended the next day, rather than following the usual process of allowing committee hearings into the Bill before third and final reading. However, GTAG member groups decided to oppose immediate passage of the Bill for which they had been campaigning, given its serious flaws, and to lobby instead for the Bill to pass through its second reading only, and then to be sent to a parliamentary committee for public hearings. This would buy time for further campaigning. Furthermore, because the government had imposed confidentiality agreements on previous consultations, it would create the first real public forum for making the case for the necessary amendments.

The opposition NDP decided to trust activists' assessment both of the flaws in the Bill and that the risk of losing the entire Bill was worth running. They noted that they would withdraw their party's consent to quick passage if this were to prove necessary, even if this meant being unfairly (and implausibly) portrayed by other parties as unsympathetic to poor patients in the developing world. Activists lobbied senior Liberal advisors as well late into the night on November 6, 2003. Ultimately, the Liberal government announced in parliament the next day that it had decided to send the Bill to committee (Chase 2003; CHLN 2003).

Subsequently, representatives from MSF and the CHLN met with senior advisors and Paul Martin, the incoming PM, to discuss concerns with the legislation as drafted. When outgoing PM Jean Chrétien prorogued parliament on November 12, 2003, Bill C-56 died on the order paper. NGOs undertook further advocacy efforts – street action, media work and lobbying – in conjunction with the LP national convention confirming Martin's election as new party leader and PM. Shortly thereafter, the media reported that Martin planned to reintroduce the bill in the next session of Parliament in early 2004 and that he acknowledged "shortcomings" in Bill C-56 as tabled (Rubec 2003).

## Resuming the fight: Bill C-9

The GTAG coalition resumed its advocacy efforts, intent on ensuring the Bill would be amended once reintroduced (CHLN 2004b; CHLN et al. 2004). NGO advocates met again with government officials for further discussions on the Bill, and the CHLN met with the office of the PM and of most of the ministers whose departments were involved. (The office of the MoI, the department with lead responsibility, did not respond to requests for a meeting.) On February 12, 2004, the text of what had previously been Bill C-56 was reintroduced in the HoC, now renumbered as Bill C-9 (PoC 2004a) and with the unusual name of the Jean Chrétien Pledge to Africa Act, in reference to the previous PM whose government had initially introduced the Bill. By way of parliamentary motion, the Bill was reinstated at the stage of hearings before the SCIST.

The CHLN prepared an information package on the Bill, including a brief highlighting four key flaws and proposed amendments, which was distributed to all MPs shortly before Committee hearings began. (For the transcript of hearings and deliberations of the Committee, see the entry Patent Act and Food and Drugs Act (amdt.) (Bill C-9) in the index of the Committee's proceedings at www.parl.gc.ca/InfoComDoc/37/3/INST/Meetings/Evidence/INSTin-E.htm.) The CHLN (2004c) also submitted an extensive series of written briefs to the Committee, complete with proposed statutory language for amendments. GTAG member groups met with many of the Committee members individually, issued numerous media releases and hosted several press conferences in their campaign to secure improvements to the legislation.

Activists focused their criticism, and their advocacy efforts, principally on four key flaws in the draft Bill:

- the "right of first refusal" provisions permitting anti-competitive action by patent holders to block licenses for generic manufacturers;
- the limited list of pharmaceutical products subject to compulsory licensing for export;
- the exclusion of developing countries that do not belong to the WTO from the list of eligible importing countries; and
- the provision specifying that only contracts between a Canadian generic supplier and a government or "agent of government" could provide the basis for a compulsory license, thereby excluding NGOs as potential purchasers of lower-cost generics from Canadian manufacturers.

Some activists also flagged their concern with the proposed requirement to have any generic drug produced under compulsory license for export undergo the same regulatory review as a drug to be marketed in Canada. While not objecting in principle to ensuring proper review of any product to be exported, advocates were concerned this could make the legislation unworkable for producing generic "fixed-dose combination" products for which there were no existing originator products already approved in Canada against which the generic product could be compared as bio-equivalent (CHLN 2004c).

At the initial round of hearings, some committee members were surprised at the depth of opposition from NGOs to provisions such as the right of first refusal. The CHLN and some other NGOs stated to the committee that if this provision were not removed from the Bill, they would prefer to see the Bill die rather than set such a poor "TRIPS-plus" precedent for implementation of the WTO Decision. In response to advocates' highly public condemnation of this provision, the patented pharmaceutical industry association (Rx&D) proposed to the SC with a so-called "alternative" – namely, a provision guaranteeing to the patent holder what it called "an equal opportunity to supply" (Rx&D 2004). Under this proposal, a Canadian generic producer would be required to notify the Canadian patent holder of any negotiations with a developing country purchaser to supply a pharmaceutical product. The patent holder would be given the opportunity at that time to bid on the contract.

After further discussion with GTAG allies, the CHLN filed a supplementary submission with the Committee rejecting the supposed alternative, arguing that the Rx&D proposal would effectively preserve the "right of first refusal" and simply amount to an "early opportunity to block competition" from generic producers. Upon being notified of a generic producer's negotiations with a potential purchaser, the patent holder would have a strong incentive to undercut any price offered by the generic manufacturer in order to maintain its market monopoly. With no contract, there would be no basis on which a generic producer could seek a license to permit manufacture and export. As with the right of first refusal, such a provision would quickly frustrate the ultimate objective of enabling sustained competitive pressure on medicine prices from generic producers and was "TRIPS-plus," unnecessarily creating "rights" for patent holders exceeding WTO requirements.

On March 18, 2004, government officials held a final round of separate consultations with "stakeholders," at which civil society advocates reiterated their opposition to the Rx&D "alternative" or similar provisions. On April 20, 2004, the SC began its clause-by-clause analysis of the draft Bill and debate on all parties' proposed amendments. The SC's debates lasted two days. On April 28, 2004, the Bill, as amended by the SC, was reported back to the HoC for a final debate and vote. Civil society organizations issued press statements indicating their mixed reactions to the Bill, with particular concern expressed about the government's insistence on preserving the schedule of pharmaceutical products (CCIC et al. 2004; MSF 2004). On May 4, 2004, Bill C-9 was put to its third and final reading and adopted unanimously by the entire House and sent to the Senate. On May 13, 2004, it received its third reading and unanimous approval in the Senate. On May 14, 2004, it received Royal Assent and thereby passed into law, making Canada the first country to enact such legislation (see PoC 2004b). Regrettably,

it was another year to the day before the government proclaimed the law into force. The accompanying regulations became effective two weeks later upon publication in the *Canada Gazette* on June 1, 2005.

## Assessment of the Canadian legislation on compulsory licensing for export

Several aspects of the legislation, as finally enacted, warrant comment here for the benefit of treatment access activists in other jurisdictions.

### Right of first refusal removed

Most importantly, the government removed the "right of first refusal" and refrained from substituting any alternative along the lines suggested by the brand-name industry, thereby avoiding setting a poor "TRIPS-plus" precedent for the implementation of the August 2003 WTO Decision. This represented a significant victory for civil society activists.

### Negotiating voluntary licenses and defining the royalty payable

TRIPS Article 31(b) says that in the ordinary course of events, before a compulsory license may be issued, the party seeking authorization to use the patented invention must first make efforts to obtain authorization from the patent holder "on reasonable commercial terms and conditions" (WTO 1994). It is only if such efforts are unsuccessful "within a reasonable period of time" (WTO 1994) that a compulsory license may then issue, with "adequate remuneration" (WTO 1994) to be payable to the patent holder according to TRIPS Article 31(h). The lack of certainty as to the meaning of these terms presents a major barrier to the likely use of compulsory licensing legislation in the litigious pharmaceutical sector. However, the Canadian legislation sets a positive precedent by bringing some welcome clarity to these vague conditions.

First, the government amended the Bill to state that, if a generic manufacturer and a patent holder are unable to agree on the terms of a voluntary license within 30 days, the CoP "shall" issue a compulsory license. This provides a clear statutory definition of the term "reasonable period of time" (WTO 1994).

Second, the legislation also effectively clarifies what constitute "reasonable terms and conditions" (WTO 1994) for a voluntary license, as well as the "adequate remuneration" (WTO 1994) that must be paid to the patent holder upon compulsory licensing. The government removed from the draft Bill the flat 2 per cent royalty rate originally specified. Instead, the final legislation simply states that the calculation of the royalty in any given case would be determined by a formula to be set out in accompanying regulations. As government officials promised before the SC, those regulations, eventually promulgated in 2005, set out a formula that consists of a sliding scale, based on the ranking of the importing country on the UNDP's HDI, with an effective cap, in the case of the country with the highest HDI ranking, of 4 per cent of the value of the contract (see Use of Patented Products for International Humanitarian Purposes Regulations,

SOR 2005/143, *Canada Gazette* (Part II), Vol. 139 (No. 11), June 1, 2005. The cap of 4 per cent was suggested by the CHALN in its first submission to the SC. This had been the standard royalty rate payable in Canada during the 1960s and 1970s when compulsory licensing was a regular feature of the Canadian pharmaceutical market under earlier versions of the Patent Act). The majority of developing and "LDCs" rank well below this on the HDI, meaning significantly lower royalties. There is no discretion on the part of the CoP to vary the royalty.

If, after 30 days, the generic manufacturer and patentee have been unable to agree on the terms of a voluntary license, the CoP "shall" issue a compulsory license, assuming the other preconditions in the legislation have been satisfied. There is no discretion vested in the Commissioner and no basis on which a patent holder can delay the process by alleging, either before the Commissioner or a court, that insufficient negotiating time had passed or that the terms last offered by the generic manufacturer are unreasonable. Similarly, by virtue clearly specifying the royalty payable upon the issuance of a compulsory license, the Canadian legislation de facto defines what constitutes a "reasonable" royalty in the event of negotiating a voluntary license.

**Limited list of pharmaceutical products**

Regrettably, the government chose to maintain a limited list of products subject to compulsory licensing. As a result, the final law includes an initial list of 56 products to which it applies, derived principally from the WHO MLEM. In response to criticism, the government added to the list all ARVs used to treat HIV/AIDS that were approved at the time for sale in Canada (with one exception).

NGOs remain(ed) critical of the list, however, because it represents a step back from the international consensus achieved with the WTO Decision. In the negotiations leading up to the Decision, several developed countries proposed to limit its scope to addressing specific diseases or just applying to specific pharmaceutical products. 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.

NGOs also argued that the bureaucratic process for expanding the list – including an advisory committee, recommendations of two ministers, and a Cabinet decision – 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 Bill in the HoC, these concerns proved well founded.

Members of the SC had discussed adding several medicines to the list annexed to the Bill. The opposition NDP proposed the addition of moxifloxacin and clarithromycin, both of which are used to treat pneumonia. Clarithromycin is also used prophylactically to prevent mycobacterium avium complex, a life-threatening infection in people living with HIV/AIDS. The government opposed adding these medicines, arguing that they were not on the WHO model list of essential medicines and claiming incorrectly that these medicines are not needed to treat HIV/AIDS, TB, or malaria. (For the transcript of HoC 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 http://www.parl.gc.ca/37/3/parlbus/chambus/house/debates/indexE/p-37–3_-e.htm.) This was in direct contradiction to repeated assurances by government officials that incorporating a list of specific products in the Bill would not be used to limit its scope solely to products on the WHO list or medicines for treating HIV/AIDS, TB, or malaria.

**Regulatory review of FDC medicines**

Canadian law generally does not require that a drug manufactured solely for export undergo the regulatory approval process that applies to drugs marketed in Canada. With Bill C-9, however, the government imposed such a review on any pharmaceutical product manufactured for export under compulsory license. NGOs supported the need to ensure quality, safety, and efficacy of any product. But they were concerned that such a requirement would end up blocking use of the law to export many FDC medicines, which combine more than one drug into a single dose. FDCs of ARVs simplify HIV/AIDS treatment regimens, and are recognized by the WHO as being critical to scaling up access to ARVs in the developing world. In the case of generic medicines being reviewed for Canadian marketing approval, standard practice is to base approval on data showing bio-equivalence of the generic product to an already approved brand-name product. But in the case of FDCs for treating HIV/AIDS, there were, at the time of Bill C-9's passage, only three such products on the Canadian market, none of which is amongst those recommended by the WHO as "first-line" therapy for use in developing country settings.

**Eligible importing countries**

The original draft Bill defined, as countries eligible to import from Canadian generic producers, all developing countries belonging to the WTO and all countries, whether belonging to the WTO or not, recognized by the UN as LDCs. While the government, in response to activists' criticism, ultimately amended the Bill to include non-WTO, non-LDC developing countries, its approach leaves something to be desired. As a result of the government's amendments, a developing country that is neither a WTO member nor an LDC can procure cheaper medicines from Canadian generic producers *only* if it satisfies the following preconditions, which are more restrictive than those facing WTO members:

- it is eligible for "official development assistance" according to the OECD (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);
- 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.

In addition, if a non-WTO developing country or LDC is added in future to the relevant schedule of countries set out in Bill C-9, 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. Furthermore, the would-be importing country must agree the product "will not be used for commercial purposes" (CHLN 2004a: 5). Under the legislation, if the country allows such use, then it may be struck off the list as a country eligible to import medicines from a Canadian generic supplier. The term "commercial purposes" is undefined in the legislation, but 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 raises questions about the distribution of imported generics via the private sector (e.g., pharmacists) in the importing country.

**NGO procurement from Canadian generic manufacturers**

Responding to civil society criticisms that NGOs could not and should not be considered to fall under the category of "agent[s] of government," the government amended the Bill to authorize generic producers to sell directly to NGO purchasers for use in eligible countries. However, the Committee accepted a motion attaching the additional, unnecessary qualification that the NGO must demonstrate it has obtained "permission" from the government of the country to import the product from the Canadian generic producer.

**Two-year limit on compulsory licenses**

The government refused to remove the provision in the Bill stating that a compulsory license may be issued for a maximum period of two years. (The compulsory license may not authorize production of the pharmaceutical product in any quantity greater than that set out in the underlying contract between the generic manufacturer and its customer. If the full quantity has not been shipped during the two-year period of the license, the generic manufacturer may apply for the license to be "renewed" (i.e., extended) once for up to another two years. This is merely an administrative provision that does not allow for any increase in the actual quantity of product produced and exported under the license. Only one renewal of a license is permitted.) After two years, the generic company must apply for a new compulsory license, based on a new contract, if it wants to continue legally to manufacture a patented product for export. To impose this cap limits the ability of a generic producer to enter into secure supply contracts with developing country purchasers for a longer period, even though negotiating longer-term contracts would provide a greater incentive for generic manufacturers to scale up production of a particular product and would permit greater economies of scale.

**Price and profit caps, an invitation to litigation**

As a result of lobbying by Rx&D, the government introduced a series of new provisions inviting patent holders to harass generic manufacturers that obtain compulsory licenses

under the legislation. The patent holder may allege in court that the generic producer's contract with a purchaser is "commercial" in nature, and seek a court order terminating the compulsory license or ordering a royalty higher than what is specified in the regulations. In its application to the court, the patent holder must allege that the generic producer is charging an average price for the product that exceeds 25 per cent of the patent holder's average price in Canada. In its defense, the generic producer must demonstrate through an audit that its average price is less than 15 per cent above its direct manufacturing costs, in which case no court order will issue.

Ostensibly, this provision in Bill C-9 seeks to control prices charged by generic producers to developing country purchasers. Yet that objective could have been achieved through other means (e.g., through conditions imposed in the grant of the compulsory license itself). Instead, the government's chosen approach invites vexatious litigation by patent holders, is potentially a disincentive to generic producers using the system, and is not required under TRIPS or the WTO Decision. It should be avoided by other countries enacting similar legislation. Giving further privileges to patent holders to litigate so as to interfere with the production and export of generic pharmaceuticals to developing countries is a poor way to follow through on stated commitments to increasing access to medicines for all.

## W(h)ither the commitment?

The legislation represents a victory of sorts for civil society advocates, without whom the law would not have existed at all and whose efforts led to important improvements to the draft Bill. But taken in its entirety, the Bill does not fully reflect the "flexibilities" allowed under TRIPS and the WTO Decision. A parliamentary review of the law is to occur in 2007, two years after its proclamation into force; that review may provide an occasion for further amendments.

How the law will play out in practice remains to be seen. Since the passage of Bill C-9 in May 2004, some NGOs have engaged generic manufacturers in Canada to determine which companies might be willing to produce which products (if any) at a price that could be attractive and feasible for developing countries or NGOs providing treatment in such countries. At the time of writing (late 2005), activists were cautiously optimistic that at least one application, for an important triple fixed-dose combination ARV, would proceed in 2006.

The extent to which the legislation is used will depend on the political pressure that civil society can bring to bear on the generic producers to test the legislation, on the brand-name pharmaceutical industry if it attempts to frustrate use of the law, and on the government to be proactive in drawing this option for securing lower-cost medicines to the attention of developing country governments and other potential beneficiaries. It will also depend on whether the global marketplace provides sufficient financial incentives for generic manufacturers, commercial enterprises whose ultimate objective is profit, to navigate the requirements of this imperfect law. It remains to be seen whether the government's repeatedly stated commitment to ensuring access to medicines for the world's poor will ultimately be undone by the compromises it introduced into

legislation. The true measure of success will be whether this law, in concert with other initiatives, ever translates into real medicines in the hands of real people.

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