
Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceuticals for export

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Abstract: In May 2004, at the urging of civil society advocates, Canada became the first country to enact detailed legislation implementing the August 2003 decision of the World Trade Organization allowing compulsory licensing of pharmaceutical patents in a WTO Member for the purpose of exporting lower-cost generic products to countries lacking sufficient capacity to manufacture their own pharmaceuticals. The Canadian legislation contains some positive features that should inform law-making elsewhere. However, it also falls short of taking full advantage of flexibilities permitted under WTO law and also contains several unnecessary, 'TRIPS-plus' provisions that should be avoided in other jurisdictions implementing the WTO Decision to promote access to more affordable medicines for all.

Keywords: pharmaceuticals; treatment access; human rights; intellectual property; patents; international law; WTO, TRIPS.

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1 Introduction

Enjoyment of the highest attainable standard of health has been recognised as a basic human right by a majority of the world's States through their ratification of the *International Covenant on Economic, Social and Cultural Rights*, whereby they have legally bound themselves to 'achieving progressively the full realisation' of this right (Article 2) by taking those steps "necessary for the prevention, treatment and control of

epidemic, endemic ... and other diseases” as well as “the creation of conditions which would assure to all medical service and medical attention in the event of sickness” (Article 12) (ICESCR, 1966). Through the UN Commission on Human Rights, among other fora, States have repeatedly declared that access to medication is a fundamental element of achieving that human right (e.g., UNCHR, 2001, 2002, 2003, 2004, 2005). Yet an estimated one-third of the world's population still lacks regular access to even those products included on the World Health Organization's Model List of Essential Medicines (WHO, 2004). Such a massive failure in achieving the human right to the highest attainable standard of health has prompted, among other important responses, increased scrutiny of the role of intellectual property rules in keeping some medicines priced out of reach for the world's majority. The conflict between the profit maximisation strategies of pharmaceutical companies supported by enhanced intellectual property regimes, and the suffering and death of millions from treatable illness, has become ever starker as the advent of the World Trade Organization's global rules for patent protection has coincided with the explosion of the global HIV/AIDS pandemic.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (WTO, 1994) requires all WTO Members to adopt certain minimum standards for protecting private intellectual property rights, including with respect to products and processes of the pharmaceutical sector. Those rules create temporary monopolies over patented pharmaceuticals, meaning the company holding the patent can charge high(er) prices. However, under TRIPS Article 31, WTO Members' domestic legislation may provide for use of a patent without the authorisation of the patentee, either through government use or through a compulsory licence issued to a third party, with payment of 'adequate remuneration' to the patentee.¹ For countries and patients that cannot easily afford higher prices charged by patentees in the exercise of their monopolies, compulsory licensing is an important policy tool to address the need for more affordable pharmaceutical products: allowing the manufacture, importation and/or sale of generic versions of a patented pharmaceutical product introduces competition and hence lower prices, of particular benefit to governments with very limited health care budgets and to the majority of people in the developing world who must pay for medicines out of their own pockets.

This presupposes that countries enjoy the necessary domestic manufacturing capacity in the pharmaceutical sector, whether through state-owned facilities or a private generic pharmaceutical industry. Many developing countries lack sufficient capacity in this sector and therefore must import pharmaceutical products. Yet TRIPS Article 31(f) originally provided that compulsory licensing may only be used 'predominantly' for the purpose of supplying the domestic market of the country in which the licence is issued.² This limited the use of compulsory licensing in those countries possessing the manufacturing capacity to produce generic pharmaceuticals for export to countries in need of imported lower-cost generics.

At their Fourth Ministerial Conference in November 2001, WTO Members recognised that, in part because of this provision, countries lacking sufficient domestic manufacturing capacity in the pharmaceutical sector faced difficulty in making effective use of compulsory licensing (WTO, 2001). They pledged to find an 'expeditious solution' to this problem. On 30th August 2003, after almost two years of bitter negotiations pitting high-income industrialised countries (and especially the US) against a bloc of developing countries and global health activists, the General Council of the World Trade Organization unanimously adopted a Decision waiving this restriction on exports (WTO,

2003; Abbott, 2005).³ As a result, WTO Members now enjoy greater freedom to permit, within their domestic law, compulsory licensing of patented pharmaceutical products for export in significant quantities to countries lacking sufficient manufacturing capacity of their own. The Decision waived, 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 Members committed themselves to finding a more permanent solution to the problem posed by Article 31(f) for countries lacking pharmaceutical manufacturing capacity and therefore facing difficulty in using compulsory licensing effectively. On 6th December 2005, WTO Members adopted a decision to amend the TRIPS Agreement by making permanent the provisions of the 30th August 2003 decision (WTO, 2005). The agreed text of the decision will be formally incorporated into the TRIPS Agreement when two-thirds of the WTO’s Members have ratified the amendment. Until that time, the interim waiver remains in effect. They have set themselves a deadline of 1st December 2007 for implementing this permanent amendment.

In September 2003, a few weeks after the WTO Decision, in response to calls from Canadian civil society organisations (e.g., Elliott, 2003a) and the UN Special Envoy on HIV/AIDS in Africa, the Government of Canada committed to enacting legislation to implement the WTO Decision through requisite reforms to Canadian law. In May 2004, after eight months of legislative drafting, intense public and private campaigning by civil society organisations, and Parliamentary committee hearings and debate, Canada passed detailed legislation aimed at implementing the General Council Decision, making it possible for generic pharmaceutical manufacturers to obtain compulsory licences to manufacture in Canada less expensive, generic versions of patented products for export to eligible countries.⁴ During this period, Canadian civil society organisations campaigned intensely to improve the bill before it passed, and succeeded in obtaining significant amendments.

Bearing the unusual name of the *Jean Chrétien Pledge to Africa (JCPA)*,⁵ in reference to the outgoing Prime Minister whose government initially introduced the bill in Parliament, the Canadian legislation set an important precedent and bears some positive features. Several flaws, however, pose potential pitfalls for those who would see the legislation used to actually generate exports of lower cost generic medicines to countries and patients in need. Consequently, it falls short of offering a ‘model’ that should simply be replicated elsewhere. This paper provides a critical analysis of the Canadian legislation in the hope that advocates and law-makers in other jurisdictions can learn from this experience, and can both draw upon the positive aspects and avoid its deficiencies.

2 From initial draft to final statute

On 6th November 2003, after two months of intense lobbying, the federal government introduced a draft bill (Bill C-56) in the House of Commons the day before the parliamentary session was to end, planning to seek all-party support for quickly passing the legislation through all three required readings by the end of the session. Given the imminent end to the parliamentary session, the agreement of all parties would have been necessary for the bill to pass quickly through Parliament within the remaining 24 hours. Canadian civil society advocates heavily criticised the bill for failing to implement the full flexibility in patent rules that had been agreed at the WTO and for giving

unwarranted, unnecessary privileges to patent-holding pharmaceutical companies that would very seriously undermine the entire initiative (Elliott, 2003b, 2003c, 2004a, 2004b). Despite having devoted considerable energy pushing for such legislation, the flaws in the government's bill were so significant that they urged all parties in the House of Commons not to give their assent to the bill, knowing that this would mean the initiative would die on the order paper at the end of the session. They urged Members of Parliament to instead pass the bill through second reading and then refer it to committee, increasing the chances that the legislation could be revived in the next session of Parliament (in early 2004) and the process could resume at the stage of committee hearings, creating an opportunity to amend the bill before passage. The opposition New Democratic Party was sympathetic to activists' criticism and indicated its willingness to withhold its consent in the House of Commons in order to possibly create an opportunity for amending the bill. In response to the criticisms and signals that all-party consent might be withheld because of the concerns expressed by civil society, the government decided to refer its bill to committee for further public discussion. On 12th February 2004, after a change in leadership of the governing Liberal Party in November 2003 and the start of a new Parliamentary session, the identical bill was re-introduced (re-numbered as Bill C-9) and hearings were held by the relevant committee of the House of Commons.

Under the aegis of the Global Treatment Action Group (GTAG), numerous civil society organisations – from human rights advocates to development NGOs, humanitarian organisations to faith-based groups, and labour unions to student groups – lobbied for amendments to Bill C-9 during the Committee hearings, and thousands of individual Canadians called, wrote or emailed the federal government and Members of Parliament to call for improvements to the legislation. A founding member of GTAG, the Canadian HIV/AIDS Legal Network prepared an information package on the bill that was distributed to every Member of Parliament shortly before Committee hearings began, made a detailed oral presentation before the Committee and an extensive series of written submissions, and met with the office of the Prime Minister and the offices of most of the Ministers of the five federal government departments involved in the drafting of the bill. Numerous other civil society organisations, and some individual experts, also appeared before the Committee and/or made submissions. GTAG member groups issued numerous media releases, hosted several press conferences, spoke with a wide variety of media outlets, and met with many of the parliamentarians on the committee to identify needed amendments to the bill.⁶ Those efforts led to some significant changes to the bill before it was enacted. On 14th May 2004, after passing through the House of Commons and the Senate, the legislation received Royal Assent and thereby passed into law.⁷

3 Positive and negative aspects of Canada's legislation

In implementing the WTO Decision of 30th August 2003, the *JCPA* amended two pieces of Canadian legislation. It introduced a new series of sections into the *Patent Act* setting out a procedure whereby an applicant may obtain from the Commissioner of Patents a compulsory licence to produce a patented pharmaceutical product for export, and establishing the parameters of such compulsory licensing. It also specified that any generic pharmaceutical product produced under a compulsory licence in Canada must

meet the same regulatory standards, under the *Food and Drugs Act*, as a product that is to be sold in the Canadian market. The *JCPA* is accompanied by three sets of regulations that were subsequently drafted, two under the *Food and Drugs Act* and one under the *Patent Act* (Government of Canada, 2005a, 2005b, 2005c).⁸

In theory, the amendments introduced by the *JCPA* make it possible for a Canadian generic pharmaceutical producer to obtain a licence to manufacture an eligible patented pharmaceutical product for export to eligible countries. How it will play out in practice remains to be seen – and will depend not only on the specifics of the legislation but also the market forces that will obviously govern the decisions of both patentees and the Canadian generic producers that might use the law. There are a number of features of the Canadian legislation that warrant comment in order to assess its merits and demerits.

3.1 Advocates' success in removing 'right of first refusal' provisions

When originally introduced in Parliament, the draft *JCPA* included a provision that would have invited Canadian patentees to engage in anti-competitive action to block generic manufacturers from obtaining compulsory licences to produce and export pharmaceutical products. Under the initial draft bill, a generic manufacturer wishing to produce a patented product for export, based on a contract negotiated with a developing country purchaser, was required to notify the Commissioner of Patents of its intent to apply for a compulsory licence, including the name of the product, the quantity to be produced, the country to which it was to be exported, and the terms and conditions of the contract between the generic manufacturer and the purchaser in question. That notice was then to be sent to the patentee, who would have 30 days to exercise one of two options: (a) voluntarily grant a licence to the generic manufacturer, in exchange for the specified royalty (then set at 2% of the value of the contract in the draft bill), limited just for the purpose of satisfying this particular contract; or (b) take over the contract negotiated by the generic producer with the purchaser on the terms agreed between the generic producer and the purchaser. Under this latter scenario, not only was the patentee entitled to take over the generic producer's contract (and, obviously, had no obligation to negotiate the terms of a voluntary licence), the Commissioner of Patents was prevented by the legislation from issuing a compulsory licence to the generic manufacturer. In other words, when faced with the prospect of a generic manufacturer seeking a licence to satisfy a sales contract it had negotiated with a customer, the patentee was given a 'right of first refusal' to decide whether it would fulfill that customer's order at the price and on the conditions it had arranged with the generic supplier.

It should be apparent that any such mechanisms would very quickly remove any incentive for generic producers to negotiate such contracts with potential customers in the first place. The company holding the patent would be able to block repeatedly a generic would-be competitor from obtaining the licence needed to make the product and fulfill the contract. In short order, there would be no potential competition from generic manufacturers and hence no competitive pressure for a patentee 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 realise the futility of trying to make the agreement work." (CGPA, 2003)

Health advocates roundly condemned this aspect of the draft legislation, calling it a 'TRIPS-plus' provision exceeding anything required by TRIPS and pointing out that it had no basis in the August 30, 2003 WTO Decision the *JCPA* was supposed to implement or in any other WTO text, and would undermine the ability of countries to make effective use of compulsory licensing in sourcing lower-cost medicines from Canadian generic suppliers (e.g., CHLN, 2004; Elliott, 2004a; CHLN/MSF, 2004). In testimony before the Parliamentary committee holding hearings into the legislation, civil society advocates expressed their deep opposition to this provision in the bill and stated that it would be better to abandon the legislation entirely than to pass it with such a profound flaw and set a negative global precedent.⁹ As a result of this and other advocacy by civil society groups, including extensive discussions with the Prime Minister's Office, the government ultimately agreed to amend the bill to remove this right of first refusal. The final legislation enacted by Parliament in May 2004 contains no such provisions; any attempt in other jurisdictions to introduce this sort of TRIPS-plus feature should be strenuously resisted as undesirable and unnecessary under WTO law.

3.2 Short time frame for requisite negotiations over a possible voluntary licence

One mostly positive feature of the Canadian legislation is its approach to the issue of negotiations between a generic manufacturer and a patentee over the terms of a possible voluntary licence. Under TRIPS Article 31(b), in the ordinary course of events, before a compulsory licence may be issued, the party seeking authorisation to use the patented invention must first make efforts to obtain authorisation from the patentee "on reasonable commercial terms and conditions". It is only if such efforts are unsuccessful "within a reasonable period of time" that a compulsory licence may then issue.

It is important to understand that this requirement to first seek a voluntary licence does *not* apply "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use" (TRIPS Article 31(b)). In such circumstances, the authorisation may be issued immediately, without any notice to the patentee or prior negotiation, although the patentee must "be notified as soon as reasonably practicable". Nor does TRIPS require efforts at prior negotiation for voluntary licence in cases where the use without the patentee's consent "is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive" (TRIPS Article 31(k)). In all cases, however, there is still a requirement to pay 'adequate remuneration' to the patentee, which is to be determined 'in the circumstances of each case' (TRIPS Article 31(h)).

The lack of certainty as to what constitutes a 'reasonable period of time' for negotiating a voluntary licence, or what constitute 'reasonable commercial terms and conditions', presents a major barrier to the likely use of compulsory licensing legislation in the heavily litigious pharmaceutical sector. Patentees have considerable incentive to drag out negotiations and to litigate any application to the competent authority for a compulsory licence, arguing that it is unreasonably premature for a generic manufacturer to have abandoned negotiations or that the generic manufacturer was unwilling to accept the patentee's 'reasonable' terms and conditions put forward in the negotiation. Such a system does not encourage the rapid, effective use of compulsory licensing that is needed to support efforts to significantly scale up access to more affordable medicines in the developing world.

Consequently, the Canadian legislation implementing the August 30, 2003 WTO Decision sets a welcome precedent in bringing some statutory clarity to these questions. It decrees that, after 30 days, if the generic manufacturer and patentee have been unable to agree on the terms of a voluntary licence, then the Commissioner of Patents ‘shall’ issue a compulsory licence (assuming the other preconditions in the legislation have been satisfied). There is no discretion vested in the Commissioner and no basis on which a patentee 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, the Canadian legislation also implicitly defines what constitutes a reasonable royalty by way of compensation to the patentee whose patented product (or process) is used by the generic manufacturer. As discussed further below, the *JCPA* and accompanying regulations under the *Patent Act* set out a formula for calculating what the royalty payable to the patentee shall be in any given case, based on the ranking on the UN’s Human Development Index (HDI) of the country for which the Canadian-made generic pharmaceuticals are destined. There is no discretion on the part of the Commissioner to vary the royalty that must be a term of the compulsory licence that issues. Clearly, then, if the law itself specifies what the royalty shall be in any given case, this effectively determines for both the generic manufacturer and the patentee what would, by default, be considered a ‘reasonable’ royalty in exchange for a voluntary licence. In the event that a patentee is unwilling to accept the royalty it has proposed, a generic manufacturer simply need wait 30 days and then its application for a compulsory licence ‘shall’ be granted, with the legislatively mandated royalty rate.

In bringing some clarity and certainty to this aspect of the compulsory licensing process, the Canadian legislation offers a useful model that can be replicated (or adapted and improved) by other jurisdictions. However, there is at least one significant shortcoming in the Canadian law as it relates to the question of prior negotiation for a possible voluntary licence. As noted above, under TRIPS, there is no need for a WTO Member to require prior negotiation with a patentee in the event of national emergency, other circumstances of extreme urgency, cases of public non-commercial use of the patented product, or when remedying the patentee’s anti-competitive behaviour. Unfortunately, the *JCPA* legislation fails to fully take advantage of this flexibility in TRIPS – even in these circumstances, it requires the generic manufacturer to request a voluntary licence from the patentee and, absent any agreement, wait the 30 days before a compulsory licence issues. In this respect, the Canadian legislation could be improved, rather than setting out what is essentially a TRIPS-plus approach.

3.3 *Products subject to compulsory licensing*

Despite consistent criticism from health advocates, the government insisted on maintaining a limited list of pharmaceutical products subject to compulsory licensing for export. The Canadian experience to date illustrates that such an approach should be avoided.

An annex to the legislation (Schedule 1) contains an initial list of 56 products to which it applies, derived principally from the World Health Organization (WHO) Model List of Essential Medicines. While civil society advocates criticised the existence of such a limited list at all, they also highlighted that most of the antiretrovirals (ARVs) used to treat people living with HIV/AIDS were not on the list. In response, the government

amended the bill to add all but one of the ARVs approved for sale in Canada at the time the legislation was enacted.¹⁰

The legislation does state that the federal Cabinet may, upon recommendation by both the Ministers of Health and Industry, add other products to the list. It provides that, with the input of relevant parliamentary committees from both the House of Commons and the Senate, an advisory committee will be established to advise the Ministers regarding which products should be added. Government officials have stated that civil society will be represented on this committee, along with people who have expertise in delivering health care in resource-poor settings. As of the time of writing, the committee had not yet been constituted, although nominations have been solicited from the patented pharmaceutical sector, generic manufacturers and civil society.

From the outset, civil society organisations were critical of the inclusion of any such list of products, because it represents a step back from the international consensus achieved with the WTO Decision in August 2003. In the negotiations leading up to the Decision, several developed countries proposed to limit its scope to just 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. By introducing a limited list of products in its implementing legislation, Canada has unilaterally undermined that consensus and set a negative precedent.

Canadian civil society groups repeatedly called on the government to abolish the list of products. They also warned that requiring a Cabinet decision to add new products would open the door to political lobbying by parent-holding brand-name pharmaceutical companies to prevent the list from being expanded, thus creating further delays in the process. In the days leading up to the final vote on the bill in the House of Commons, these concerns proved to be well founded, as illustrated by the first attempt to expand the list.

Members of the Parliamentary committee that reviewed the bill had discussed adding several medicines to the list annexed to the bill. The opposition New Democratic Party (NDP) had proposed that the added drugs include moxifloxacin and clarithromycin, both of which are used to treat pneumonia, a condition of particular significance to people with compromised immune systems. Clarithromycin is also used prophylactically to prevent mycobacterium avium complex (MAC), a life-threatening infection in people living with HIV/AIDS. A version of clarithromycin produced by an Indian generic manufacturer is among the HIV/AIDS medicines pre-qualified by the World Health Organization as meeting the WHO's quality standards. At the Standing Committee, all political parties agreed that, absent any technical objections by Health Canada (the federal department of health) to a particular drug, the additional medicines under discussion would be added to the bill by motion when it came before the House of Commons for final reading and adoption.

Health Canada indicated that it had no objection to the addition of either moxifloxacin or clarithromycin to the schedule in Bill C-9. But the NDP subsequently received calls from Bayer, the pharmaceutical company that holds the Canadian patent on the drug moxifloxacin, objecting to its inclusion in Bill C-9. At least one pharmaceutical company also contacted Ministers' offices objecting to the addition of any medicines to the list (McGregor, 2004). Following pressure from the pharmaceutical industry, a Minister's office subsequently contacted the NDP to request that they withdraw some of

its motions to add specific drugs – products that all parties had already agreed would be added. The NDP rejected this request.

Subsequently, during the consideration of these motions on the floor of the House of Commons, the governing Liberal Party argued against the addition of these medicines to the list of products covered by the bill. Government representatives stated during the Parliamentary debate that moxifloxacin and clarithromycin were not on the WHO model list of essential medicines, and claimed (incorrectly) that these medicines were not needed to treat HIV/AIDS, TB or malaria.¹¹ This was in direct contradiction to assurances that government officials had made repeatedly to health advocates, namely that including a list of specific products in the bill would not be used to limit the scope of the legislation to just products on the WHO list or just medicines for treating people living with HIV/AIDS, TB or malaria.

This experience illustrates the pitfalls of having such a list of products, and calls into question the good faith of the government in promising that the list would not limit the scope of Canada's initiative. This does not bode well for future efforts to add to the list of products eligible for compulsory licensing and export. It also provides an important lesson that any mechanism for limiting the scope of compulsory licensing legislation to specific pharmaceutical products, which is not only unnecessary under the WTO Decision but contrary to its very spirit, should be rejected.

3.4 *Fixed-dose combination medicines (FDCs)*

Another concern raised by the Canadian approach is whether it will prove flexible enough to enable the easy production of some of the lower-cost generic medicines needed most, namely fixed dose combinations (FDCs) that combine more than one drug into a single tablet or formulation. FDCs of ARVs simplify treatment regimens, and are recognised by the WHO as being of critical importance in its efforts to dramatically scale up access to ARVs in the developing world. Aside from the *JCPA*, Canadian law does not require that a drug manufactured solely for export undergo the regulatory approval process that applies to drugs marketed in Canada. However, the *JCPA* imposes such a review on any pharmaceutical product manufactured under compulsory licence for export. Such a review is required only for drugs produced under compulsory licence, creating another hurdle. It remains to be seen how the drug regulatory authority will, in practice, handle the case where a Canadian generic manufacturer seeks a compulsory licence to produce and export an FDC product that is a combination not yet produced by patentees and approved for marketing in Canada.

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 are only three such products on the Canadian market. Two of these (Combivir® and Trizivir®) combine drugs patented by GlaxoSmithKline; the third (Kaletra™) combines two drugs patented by Abbott. These combination products are important, but are not among those recommended as 'first-line' therapy by the WHO for use in resource-poor settings. The first-line products are currently only available from generic producers in countries such as India, where the individual constituent drugs have not, until recently, been patent protected, making it possible to engineer their combination without infringing patents.¹²

Canada has insisted that any generic pharmaceutical produced for export under compulsory licence meet Canadian marketing approval standards – rather than, for example, allowing ‘pre-qualification’ of the product and the manufacturer by the WHO’s Prequalification Project to suffice.¹³ Consequently, the onus is on the government to ensure that the process is rapid, transparent and not overly cumbersome – particularly when it comes to enabling the production and export of products such as FDCs, which are a priority in the global effort to scale up treatment access.

Under Canadian law, in the ordinary course of events, when a manufacturer seeks marketing approval for its generic version of an existing brand-name drug already approved for sale in Canada (the ‘reference product’), it is permitted to file an ‘abbreviated new drug submission’ with the necessary data to show that its product is ‘bioequivalent’ to the reference product. It need not submit the full dossier showing anew the safety and efficacy of the product, because this has already been satisfactorily established in the review of the original product. In the regulations subsequently drafted to complement the *JCPA*, the government has chosen to treat any FDC for which no Canadian ‘reference product’ has already received approval as a ‘new drug’ requiring a full ‘new drug submission’ for regulatory review, in contrast to accepting an ‘abbreviated’ new drug submission (Government of Canada, 2005b). The rationale is that the combination of these drugs into a single formulation creates a ‘new’ product because of potential interactions between the components, changes to the stability of the formulation, etc. Health advocates have raised the concern that insisting on the full-scale review process required for a ‘new’ drug, with the attendant delay and potential expense, could prove to be a significant disincentive to generic manufacturers contemplating using the legislative scheme to manufacture FDCs which are needed in developing countries but which have not yet been manufactured and marketed through collaboration between the various brand-name companies holding the patents on different drugs in the combination, and have argued for flexibility (MSF, 2005).

In response, Health Canada’s Therapeutic Products Directorate (TPD) has provided assurances that, although it must treat such FDCs as ‘new’ drugs under the *Food and Drugs Act* and the *Food and Drug Regulations*, its policies and its practice will be sufficiently flexible so as not to require the full range of clinical trial and other data that would normally be the standard for reviewing a new drug. Instead, in conducting its risk/benefit assessment of the safety and efficacy of the new FDC product, Health Canada will allow for marketing approval based on bio-availability studies and other evidence in support of the use of the combination (e.g., clinical data from patients who are receiving each of the combination’s drugs separately). Health Canada has also established a separate ‘fast-track’ procedure for reviewing applications for marketing approval in relation to any drug for which a compulsory licence is sought to produce for export under the scheme established by the *JCPA*. The first application for a compulsory licence under the new legislation may be filed in 2006, involving a triple fixed-dose combination ARV being developed by a large Canadian generic drug manufacturer. This will be the first test of the regulatory authority’s stated flexibility and speed in reviewing this ‘new drug’ under the *JCPA* regime.

3.5 *Countries to which generics produced under compulsory licence may be exported*

At the time of the WTO Decision, WTO member countries had been divided into various categories for the purposes of using the Decision to import generic pharmaceuticals. This division was reflected in a Chairperson's Statement placed on the record, at the request of the US, in conjunction with the adoption by the WTO General Council of the Decision itself. (The legal status of that Statement remains a matter of debate). Twenty-three high-income countries agreed to opt out of using the Decision to import generic medicines produced under compulsory licences.¹⁴ Eleven middle-income countries stated that they would only use the Decision to import generic medicines produced under compulsory licence in situations of national emergency or other circumstances of extreme urgency.¹⁵ Ten Eastern European or Baltic countries made a similar statement, further indicating that they would opt out of importing entirely upon acceding to the European Union.¹⁶ This decision has been criticised as a short-sighted sop to the brand-name pharmaceutical industry, given the uncertain future needs of these countries' populations in the event, for example, of a significant outbreak of a communicable disease such as SARS, influenza or other pathogen.

This division of WTO Members into different categories is reflected in the different country schedules attached to the Canadian legislation (Schedules 2–4), which set out different groups of countries to which, under various conditions, generic pharmaceuticals made in Canada under a compulsory licence may be exported. When the legislation was first introduced, the government had chosen, in part because of submissions from civil society advocates, to include, as eligible importers of Canadian generics, every country then recognised as a 'least-developed country' (LDCs) by the United Nations, regardless of whether it was a WTO Member or not. This was an important step, but raised the question of why 'developing countries' (other than those which are LDCs) were not also included as eligible importers of Canadian generics unless they belong to the WTO. Civil society advocates argued that access by people in the developing world to lower-cost generic medicines should not depend on whether their country belongs to the WTO. They also pointed out that nothing in WTO law (including the August 30, 2003 Decision of the General Council that is the basis of the legislation) prohibited Canada from implementing the Decision in a manner that authorises compulsory licensing of pharmaceuticals for export to *non*-WTO developing countries as well (e.g., CHLN, 2004). As a result of that advocacy, the government agreed to certain amendments, with the result that the Canadian legislation sets a positive precedent by affirming that countries implementing the WTO Decision can authorise production of generics for export to non-WTO countries. (This approach has subsequently been affirmed by some other jurisdictions that have drafted or implemented legislation or regulations pursuant to the WTO Decision).

However, the approach ultimately adopted by the government on this point leaves something to be desired. A developing country that is neither a WTO Member nor an LDC can procure cheaper medicines from Canadian generic producers *only* if:

- it is eligible for 'official development assistance' according to the Organization for Economic Cooperation and Development (OECD)¹⁷
- it declares a 'national emergency or other circumstances of extreme urgency'
- it specifies the name and quantity of a specific product needed for dealing with that emergency.

This approach creates an indefensible double standard between developing countries that belong to the WTO and those that do not. In the negotiations leading to the WTO Decision, developing country Members firmly rejected efforts to limit their use of compulsory licensing to import generic medicines only in 'emergency' situations. Health activists also rejected such proposals as unsound health policy and unethical. The final WTO Decision adopted on August 30, 2003 does not impose such a limitation. It respects Members' sovereignty as set out in the TRIPS Agreement and it re-affirms the statement in the November 2001 Doha Declaration to the effect that countries are free to determine for themselves the grounds upon which to use compulsory licensing.

For the most part, thanks to advocacy by civil society groups, the Canadian legislation does not limit the use of compulsory licensing of pharmaceuticals to only allow exports to countries facing 'emergencies'. Imposing such a restriction was the original intent of the government, in a blatant attempt to renege on the multilateral consensus achieved in the August 30, 2003 WTO Decision after months of acrimonious debate in which just such a limitation had been a major point of contention. But criticism from activists led to a change in the government position that was ultimately reflected in the legislation tabled in Parliament (e.g., CHLN/MSF, 2003). The TRIPS Agreement, and the subsequent November 2001 Doha Declaration on the TRIPS Agreement and Public Health, make it clear that compulsory licensing as a policy tool is *not* limited only to dealing with emergency situations, although this is a common misinterpretation, whether deliberate or careless, in much commentary.

Notwithstanding the clear state of WTO law, and the sensitive nature of this point in the negotiations that ultimately produced the August 30, 2003 Decision, the government chose to insist on this 'emergency' limitation when amending the draft *JCPA* to add to the list of eligible importing countries the over 20 developing countries that are neither WTO Members nor LDCs. This is at odds with the spirit of the consensus achieved in the WTO Decision and is an embarrassing demonstration of bad faith in the Canadian legislation.

In addition, if a non-WTO developing country or LDC is added in future to the relevant schedule of countries set out in the *JCPA*, that country 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, it must agree the product "will not be used for commercial purposes". 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 also raises questions about the distribution of imported generics via the private sector (e.g., pharmacists) in the importing country. Will this be considered a 'commercial purpose'? If so, such a provision fails to recognise the reality that many people in developing countries, as elsewhere, need to turn to private pharmacies when

purchasing medicines, which are also frequently paid for out of their own pocket rather than covered by a public scheme. This provision is unnecessary under TRIPS and the WTO Decision; it should not have been included in the Canadian legislation, nor should this approach be replicated by other jurisdictions.

3.6 Eligible purchasers of Canadian generics

Originally, the *JCPA* contained no provision that would allow anyone other than a 'government agent' to purchase medicines from a Canadian generic producer; non-governmental organisations (e.g., Médecins Sans Frontières) and international agencies that often play a key role in procuring and delivering medicines to patients in need would not have been able to benefit from this legislation. In response to criticism by NGOs that this limitation was unnecessary and unhelpful, the Government brought forward an amendment that would have solved this problem.

Sadly, it allowed its own positive change to be largely gutted by a further amendment from one of its own party members at the Parliamentary committee stage, and then rejected requests that it revert to its own original amendment without qualification. As a result, under the final text of the *JCPA* as enacted, any NGO in a developing country that wants to purchase medicines from a Canadian generic producer and import them must obtain the 'permission' of the government of that country. 'Permission' is not defined in the legislation.

This requirement applies even if the product is already approved for sale in the developing country by the drug regulatory authority, and even if there is no patent barrier to importing the product (either because it is not patented in the country or the NGO has obtained a compulsory licence from the appropriate authority under the country's legislation that authorises it to import the product). This requirement creates an additional hurdle that is not required by the WTO Decision of August 30, 2003 or any other WTO instrument, thus further delaying what is supposed to be a rapid response. Furthermore, it exposes NGOs to political manipulation by governments who may have some irrational ideological opposition to certain medicines (e.g., the South African government's bizarre and persistent recalcitrance in scaling up access to ARV therapy for people living with HIV/AIDS) or who may wish to penalise NGOs that it finds objectionable (e.g., because of their criticism of some government policy or practice). It should be noted that it would be contrary to States' obligations under international human rights law to engage in such tactics, as it would be contrary to the obligation to progressively realise the right to health (CESCR, 1990, 2000).

3.7 'Adequate remuneration' to patentee in event of compulsory licensing

On the positive side, Canada's legislation sets a reasonably good precedent in its approach to the royalties payable to a patent-holder. The original bill had proposed a standard royalty rate of 2% of the value of the contract to be paid to the Canadian patent-holder. The brand-name pharmaceutical companies objected, concerned that this would set a precedent they considered undesirable – they took issue both with the notion of a flat rate and the rate itself. Generic producers and civil society organisations supported the approach in the draft bill, but were also agreeable to a sliding scale, as long as the rate in any given case was predictable and as long as there was an overall cap on the royalty to keep the costs of using this system minimal. They made submissions to this

effect before the Parliamentary committee during its hearings into the legislation (e.g., CHLN, 2004).

In the result, the government stated to the committee that it would amend the bill to establish a sliding scale formula linking the royalty rate in any given case to the ranking of the importing country on the UN Development Program's Human Development Index (HDI). The final text brought before Parliament for enactment was amended to remove the reference to a flat royalty rate of 2%; instead, the formula for the sliding scale royalty rate was to be set out in subsequent regulations. Under those regulations, which came into force on June 1, 2005, the effective cap will be 4% of the value of the contract in the case of the country with the highest HDI ranking (Government of Canada, 2004a). Obviously, the majority of developing and least developed countries that are eligible importers from Canadian generic manufacturers rank well below this on the HDI, meaning royalties in those instances will be significantly lower.

This approach to the royalty rates, although still not perfect (e.g., in how it treats the situation of an importing country without an HDI ranking) is one of the most positive features of the Canadian legislation and is worthy of study by legislators and advocates in other jurisdictions as one possible model.

3.8 Two-year limit on compulsory licences

From the outset, the government drafters insisted that the legislation limit the term of any compulsory licence that might be issued to a period of two years, ostensibly on the theory that parties to a contract for the purchase and provision of pharmaceuticals should not be locked into an arrangement for longer than this time frame and should have flexibility to respond to changing developments such as advances in treatment. Such a paternalistic approach, trying to legislate by proxy a limit on the term of a contract, seems strange given the government's general unwillingness to interfere with parties' freedom to bargain in the marketplace. There is little reason to believe that developing countries (or other bulk purchasers of pharmaceuticals) are unable to adequately assess and project their own medicine needs and contract accordingly. Furthermore, such a proposition is irrelevant to the issue of compulsory licensing; should this argument not also be applicable in every situation where a developing country is purchasing medicines from a pharmaceutical supplier, be it a brand-name company or a generic one? The fact that a generic producer may, in respect of a specific drug that is still patented in Canada, need a compulsory licence to manufacture and supply that medicine is a secondary consideration. It seems, rather, that this cap represents a misguided and unnecessary attempt to constrain generic producers' ability to compete effectively in the marketplace, by limiting the term of a compulsory licence available under the legislation.

Civil society advocates rejected the government's stated rationale for such a cap and argued that it was arbitrary and irrational, and could seriously undermine the legislation because it would function as a (further) disincentive to generic manufacturers using the system: if they could only secure the right to manufacture a given drug for a two year period, this severely limits the likelihood of being able to negotiate a contract that allows for economies of scale and that generates a revenue stream worth the start-up expense of manufacturing a generic version of the drug in question. Advocates argued instead that a compulsory licence should either run for the remaining term of the patent or at least be coterminous with the length of the contract negotiated between the generic manufacturer and the purchaser, which contract is the basis of the application to the Commissioner of

Patents for a compulsory licence. Rather than using arbitrary limits in the compulsory licensing law to attempt unjustifiably to dictate contract terms between generic suppliers and purchasers, the compulsory licensing regime would respond to the arrangement they have negotiated. Recall that the August 30, 2003 WTO Decision was intended to address, in the words of WTO Members' own 2001 Declaration on the TRIPS Agreement and Public Health, the difficulties faced by countries lacking sufficient pharmaceutical manufacturing capacity in "making effective use of compulsory licensing" to protect health by promoting access to medicines for all. Ensuring the compulsory licensing regime facilitates their freely negotiated initiatives for cheaper medicines is a more rational approach than letting the patent law tail wag the health promotion dog.

Unfortunately, in the final result, the Canadian legislation maintains the two year limit on the term of a compulsory licence. (It does provide for the possibility of one easily obtained 'renewal' of the licence, but only for the purpose of extending the timeframe during which the generic manufacturer may manufacture and deliver the quantity originally agreed with the purchaser and authorised by the compulsory licence when first issued). After the two year period has elapsed, should a generic manufacturer wish to continue manufacturing the patented product for export – e.g., to continue supplying the same purchaser or to supply to other customers it has secured – it must submit a fresh application for a new compulsory licence. It remains to be seen whether and to what extent Canadian patentees will use this provision to game the system – for example, by undercutting the generic's price offer to the potential purchaser in the lead-up to the expiry of the first two-year licence, or by taking advantage of provisions under other Canadian regulations that could be used to interfere with the grant of a second compulsory licence to the generic manufacturer (e.g., by changing the shape, colour or markings of their product sold in Canada, from which the generic manufacturer is required by the *JCPA* to distinguish its product before it can obtain a compulsory licence).

3.9 *Legislated caps on generic manufacturers' prices and profit margins*

Sadly, the Canadian legislation contains unnecessary provisions that function chiefly as an invitation to patentees to initiate litigation against generics operating under compulsory licences – a further disincentive to using the legislative scheme created by the Act. Under the *JCPA*, the Canadian patent-holder may apply for a court order terminating a compulsory licence or ordering a higher royalty (than what is specified by the sliding scale in the regulations) on the basis that a generic company's contract with a purchaser is 'commercial' in nature as opposed to 'humanitarian'. 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% of the patent-holder's average price in Canada. As long as the generic producer can demonstrate, through an audit, that its average price is less than 15% above its direct manufacturing costs, the court may not issue such an order revoking the licence or raising the royalty payable to the patentee.

Although this provision in the *JCPA* is ostensibly aimed at controlling prices charged by generic producers to developing country purchasers, that objective could have been achieved through other means (such as through conditions imposed in the grant of the compulsory licence itself). This aspect of the law 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 harass generic producers that are issued compulsory licences, and to interfere with 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.

4 Conclusion

On the positive side, the Canadian legislation on compulsory licensing for export provides useful clarity on the contentious questions of determining the 'adequate remuneration' payable to patentees and the time that must be spent, in the ordinary course, in negotiating with a patentee before a compulsory licence may issue. The chief defects of Canada's law on compulsory licensing of pharmaceuticals for export are two-fold: (i) it falls short of fully reflecting the 'flexibilities' allowed under WTO law; and (ii) it contains some TRIPS-plus features that undermine its functionality. As the first detailed legislative model for implementing the WTO General Council Decision of August 30, 2003, the Canadian initiative is an important one, as part of an overall global effort to improve access to medicines. But it can and must be improved. A Parliamentary review of the law is scheduled to occur in 2007, at which point recommendations could lead to further amendments depending on political will. In the interim, other countries moving to implement the WTO Decision should learn from the Canadian experience.

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Notes

¹For convenience, the term 'compulsory licensing' will be used here to refer both to government use of a patent and use by a third party holding a licence obtained without the consent of the patentee.

²This limitation does not apply if the licence is issued to remedy practices by the patent holder that have been determined after judicial or administrative process to be anti-competitive: TRIPS Article 31(k).

³For a detailed discussion of this Decision and the process that led to it, see Abbott (2005).

⁴The government did not actually proclaim the legislation into force until one year later (14th May 2005), because of delays in drafting the requisite regulations to accompany the new statutory provisions and because of government and Parliamentary delays in enacting a bill with some minor technical amendments to the original legislation.

⁵An Act to Amend the Patent Act and the Food and Drugs Act (the Jean Chrétien Pledge to Africa Act), S.C. 2004, c.23. The text of the *Jean Chrétien Pledge to Africa Act* can be found at <http://laws.justice.gc.ca/en/2004/23/2539.html>. For a quick summary of the legislation, see www.parl.gc.ca/37/3/parlbus/chambus/house/bills/summaries/c9-e.pdf. Extensive additional materials are available on the website of the Canadian HIV/AIDS Legal Network at <http://www.aidslaw.ca/>.

⁶Most of these materials can be accessed online at www.aidslaw.ca.

⁷On the same day, Norway promulgated changes to regulations under its Patent Act to implement the WTO Decision, although with far less detail. Those regulations were scheduled to come into force on 1st June 2004 (Permanent Mission of Norway, 2004). The text is available online at: <http://lists.essential.org/pipermail/ip-health/2004-July/006812.html>. Subsequently, a number of other jurisdictions have either introduced or implemented legislation or regulations to implement the WTO Decision. On 16th July 2004, the US and Canada adopted a Memorandum of Understanding agreeing that the intellectual property provisions of the North American Free Trade Agreement (NAFTA) would not be applied so as to block the implementation of Canada's Bill C-9 (see: Letter from R. Zoellick, US Trade Representative to Hon. J. Peterson, Canadian Minister for International Trade, 16th July 2004, available via www.aidslaw.ca). There has been no real concern that Mexico, the other signatory to NAFTA, would raise any objections to the Canadian legislation under NAFTA.

⁸The complete text of the regulations was published on June 1, 2005 in the Canada Gazette (available online at <http://canadagazette.gc.ca/partII/2005/20050601/html/index-e.html>).

⁹For example, see testimony on February 26, 2004 by the representative of the Canadian HIV/AIDS Legal Network before the House of Commons Standing Committee on Industry, Science and Technology (37th Parliament, 3rd Session), available on the Parliamentary website at www.parl.gc.ca. See also MSF/CHLN (2004).

¹⁰The ARV enfurvitide (also known as Fuzeon or T-20), an expensive drug in the new class of fusion inhibitors, was not included on the list. Fuzeon, a medication administered through injection, was approved for sale in Canada by Health Canada's Therapeutic Products Directorate in July 2003, but government officials took the view that the drug had only recently been approved in Canada, meaning there was not the same degree of post-marketing experience with its use, and it was principally prescribed (at the time) as a component of 'salvage therapy' for patients who had developed resistance to other classes of antiretrovirals. Furthermore they expressed concern about the suitability of exporting a drug administered by injection for use in settings where the infrastructure for delivering such a medicine safely and effectively (e.g., access to sterile syringes) may be limited.

¹¹For the transcript of House of Commons debates over Bill C-9, see the entry 'Patent Act and Food and Drugs Act (amdt.)' in the index to Hansard, the record of chamber business, at www.parl.gc.ca/37/3/parlbus/chambus/house/debates/indexE/p-37-3_-e.htm.

¹²As of January 1, 2005, India was required to bring its domestic legislation into compliance with TRIPS, including extending product patents for pharmaceuticals. Under The Patents (Amendments) Act, 2005, passed by the Indian Parliament in March 2005, patent protection for pharmaceutical products is now a feature of Indian law. The legislation's impact upon the continued production of generics in the case of existing ARVs is uncertain at this time. Similarly, in the case of new ARVs that will now be patentable in India (whether single or combination products), it remains to be seen whether the provisions included in the legislation to reflect the WTO Decision of August 30, 2003 on compulsory licensing will, in practice, be workable and permit the ongoing manufacture and export of generic products, including FDCs, by Indian producers.

¹³See the website of the WHO Prequalification Project at <http://mednet3.who.int/prequal/>. The Project has already prequalified several FDCs from generic manufacturers.

¹⁴The countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, UK and USA.

¹⁵The countries are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and UAE.

¹⁶The countries are Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia. Accession occurred on 1st May 2004.

¹⁷In 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.