Global Access to Medicines: Will Canada Meet the Challenge?

Supplementary submission to the Standing Committee on Industry, Science and Technology on Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act

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INTRODUCTION

The Canadian HIV/AIDS Legal Network welcomes this opportunity to provide further submissions to the Standing Committee during its deliberations regarding Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act.

The Standing Committee has asked that we provide our views regarding the "alternatives" to the right of refusal that have been put forward by other witnesses appearing before the Committee. We address several of the most important points that have been put before the Committee.

The purpose of Bill C-9 is to implement the WTO Decision of 30 August 2003. That WTO Decision was aimed at enabling countries lacking sufficient pharmaceutical manufacturing capacity to "make effective use of compulsory licensing" (Doha Declaration, paragraph 6) to obtain less expensive pharmaceutical products.

Bill C-9 should implement the WTO Decision without adding additional procedural requirements or additional entitlements for patent holders, as these will frustrate the effective implementation of the Decision and will undermine the ability of countries to make effective use of compulsory licensing to foster market competition that will bring prices of medicines down.

1. "EQUAL OPPORTUNITY TO SUPPLY COUNTRIES IN NEED" AMOUNTS TO AN "EARLY OPPORTUNITY TO BLOCK COMPETITION" IN THE MARKET

In its recent submission to the Standing Committee, Canada's Research-based Pharmaceutical Companies (R_x&D) have proposed what they characterize as an "alternative" to the right of refusal as it currently appears in Bill C-9. However, the proposed alternative amounts to substantially the same right of refusal as is already found in Bill C-9, and suffers from the same fundamental flaws. Those flaws are:

(1) The R_x&D proposal in essence preserves a "right of refusal" that authorizes, and indeed invites, anti-competitive practices by the patent-holder in order to completely block a would-be generic competitor from being able to enter the market.

(2) The R_x&D proposal still represents a "TRIPS-plus" provision that creates additional entitlements for patent holders beyond what is required by the WTO TRIPS Agreement and the WTO Decision of 30 August 2003. Were Canada to accept such a proposal, it would actually enhance patent barriers to accessing medicines. This would establish a very damaging global precedent in the implementation of that WTO Decision, the very purpose of which is to enable countries to limit patent rights when they determine this to be necessary to protect public health and promote access to affordable medicines.

(1) R_x&D proposal still amounts to a 'right of refusal' exercised to block competition

In essence, the R_x&D proposal maintains a right of first refusal, that it can exercise to block competition in the market, but simply allows the patent-holder to exercise that right at an earlier stage in the process. What R_x&D characterizes as an "equal opportunity" to supply countries in need will chiefly amount to an early opportunity for a patent-holder to block competition from generic producers.

Under Bill C-9 as it currently stands, the patent-holder is given the right to take over a contract *after* it has been negotiated between a generic company and a developing country purchaser.

Under the "alternative" proposed by R_x&D, a Canadian generic producer would be required to notify the Canadian patent holder of any negotiations it undertakes 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.

In any given case, the patent holder will have a strong incentive to undercut any price offered by the generic manufacturer in order to maintain its market monopoly. With no contract, there will be no basis on which a generic producer could seek a licence to permit manufacture and export.

As with the right of refusal currently found in Bill C-9, this system may produce a handful of initial cases where, through this bidding process, a particular developing country obtains a particular medicine, for a limited period of time, at a lower price than might otherwise have been the case.

However, in very short order, having been repeatedly blocked from entering the market, generic producers will have no incentive to even attempt to negotiate contracts with developing country purchasers. Any competitive pressure on the patent holder to lower prices will then disappear, with market monopolies intact.

This effectively precludes the competition that is needed to bring prices down and keep them down, and thereby undermines the goal of supporting developing countries in implementing policies that will improve ***sustainable*** access to affordable medicines. We note that expert submissions received by the Committee demonstrate that it is generic competition – including competition among multiple generic producers – that leads to sustained decreases in market prices of pharmaceuticals.[1]

[1] Joel Lexchin, MD, Associate Professor, School of Health Policy and Management, York University. Brief to the Industry, Science and Technology Committee on Bill C-9, February 23, 2004.

The very purpose of Bill C-9, in implementing the WTO Decision of 30 August 2003, is to allow developing countries to make effective use of compulsory licensing to create that market competition. The "alternative" proposed by R_x&D would, just as much as the right of refusal as it currently appears in Bill C-9, still frustrate the very objective of this legislation.

What Rx&D characterizes as an "equal opportunity" to supply countries in need will chiefly amount to an early opportunity for a patent-holder to block competition from generic producers.

(2) R_x&D proposal is unnecessary and still goes beyond WTO requirements

The R_x&D proposal still represents a "TRIPS-plus" provision that creates additional entitlements for patent holders beyond what is required by the WTO TRIPS Agreement and the WTO Decision of 30 August 2003. This would establish a very negative global precedent in the implementation of that WTO Decision, the purpose of which is to enable countries to effectively limit patent rights, through compulsory licensing, when they find this necessary to protect public health and promote access to affordable medicines.

As R_x&D acknowledges in its own brief, "the WTO process as currently envisaged does not mandate an open bidding process for every contract. It simply mandates that its members post the terms of the contract once finalized." But by creating a legal obligation for a generic producer to notify a patentee of any contract negotiations it is undertaking, R_x&D's proposal seeks to create an additional right for the patent-holder, which it admits is not found in WTO intellectual property law, and which would give it yet another opportunity to block a would-be competitor from getting a licence.

Such an opportunity is not to be found anywhere in the WTO Decision of 30 August 2003, unanimously adopted by WTO Members, that Bill C-9 is supposed to implement. Furthermore, what R_x&D is proposing runs directly contrary to the spirit of the Doha Declaration of November

2001, in which WTO Members unanimously agreed that: countries are free to determine for themselves when and how to use compulsory licensing (paragraph 5); the TRIPS Agreement should be interpreted and implemented in a manner that supports Members' right to promote access to medicines for all (paragraph 4); and they would solve the problem that countries with insufficient manufacturing capacity face difficulty in "making effective use of compulsory licensing" (paragraph 6).

What TRIPS requires –and why TRIPS does not require a "right of refusal"

All that the TRIPS Agreement – and specifically Article 31(b) requires – is that, before a compulsory licence is issued, there are efforts made to first obtain a voluntary licence from the patent holder "on reasonable commercial terms".[2] If those efforts are unsuccessful within a "reasonable period of time", then a compulsory licence may be issued and the issuing authority fixes the royalty appropriate in the circumstances. One way or the other, however, the generic producer is able to obtain a licence – whether voluntarily granted by the patent holder or a compulsory once issued by the competent authority – and the patent-holder receives adequate remuneration in exchange. This is all that TRIPS requires.

Thus, the only "right of refusal" required by TRIPS is that the holder of the Canadian patent is given a right to refuse to issue a voluntary licence if it does not feel the commercial terms proposed are reasonable. It is then up to the Commissioner of Patents to determine whether to issue a compulsory licence and the royalty rate appropriate in the circumstances.

TRIPS does <u>not</u> require that a patent holder be given the "right" to take over contracts that have been negotiated by a generic producer (as is currently proposed in Bill C-9), nor does it require that the patent holder be given notification of any negotiations that a generic company is undertaking with a purchaser and the opportunity to block the generic company from entering the market.

[2] Under TRIPS Article 31, this requirement to first seek a voluntary licence does not apply in cases of national emergency, other circumstances of extreme urgency, public non-commercial use, or in the case of issuing a compulsory licence to remedy anti-competitive practices.

(3) A better, more TRIPS-compliant and effective proposal

The Canadian HIV/AIDS Legal Network has proposed a system that:

- more faithfully reflects the requirements of the TRIPS Agreement than either the current Bill C-9 or the "alternative" proposals that have been put before the Committee;

- is more in line with both the Doha Declaration of November 2001 and the WTO Decision of 30 August 2003, which Bill C-9 is supposed to implement; and

- will be more streamlined and effective in achieving the objective of enabling countries lacking manufacturing capacity to "make effective use" of compulsory licensing to foster the competition in the marketplace which brings medicine prices down.

The Legal Network has proposed that Bill C-9 provide that, after a Canadian generic company has negotiated a contract with a developing country purchaser, the following should occur:

(1) The patent-holder is notified of the generic company's request for a licence to produce the product.

(2) The patent holder has 30 days to decide whether it will grant a voluntary licence to the generic producer, at the statutorily determined royalty of 2%, or refuse to grant that licence. (This is permitted under TRIPS Article 31(b) which simply requires that the licence be on "reasonable commercial terms". It is open to Canada to define this as meaning a 2% royalty in the event of a voluntary licence from the patent-holder, given the purpose of the licence is to allow supply of a generic product to a developing country.) This right to refuse to grant a voluntary licence at a royalty rate of 2% is the only "right of refusal" required by the TRIPS Agreement (and is not required in cases of national emergency, other circumstances of extreme urgency, or for public non-commercial use.)

(3) If the patent holder refuses to grant a voluntary licence within 30 days, the Commissioner of Patents may grant a compulsory licence and fix the royalty rate as appropriate in the circumstances. Under the TRIPS Agreement, when a compulsory licence is issued, the patent holder is entitled to "adequate remuneration in the circumstances of each case". The bill would therefore set out criteria to be applied by the Commissioner in determining the appropriate royalty that would provide "adequate remuneration". The patent holder and the generic producer could make submissions as to the appropriate royalty, but it would be statutorily capped at 4%. (This was the standard royalty rate previously under Canadian law in the case of compulsory licences to supply the Canadian market; in the case of licences to supply poorer countries, the royalty rate should be no more than this.)

Our proposal would respect Canada's TRIPS obligations regarding compulsory licensing and would ensure that the patent-holder receives the "adequate remuneration" to which it is entitled. But it would also ensure that a generic pharmaceutical manufacturer can, one way or the other, obtain either a voluntary or a compulsory licence, and can therefore follow through on contracts it negotiates with a developing country purchaser. It would not give a patent-holder additional "rights" which do not appear in any of the WTO treaties and decisions which Canada has endorsed and that would authorize and invite anti-competitive practices to block generic producers from entering the market to supply developing countries.

2. ADMINISTRATIVE AMENDMENTS:

TIME LIMITS ON LICENCES AND LIMITS ON RENEWALS

R_x&D has submitted that any licence issued to a generic producer must be limited to 2 years, and should only be renewable once. The Committee should reject this submission, as these proposals will only make the system more cumbersome and more ineffective.

As we have submitted, it is arbitrary and irrational to limit the term of a compulsory licence to only 2 years. The point of the compulsory licence is to allow the Canadian generic producer to fulfil its contract with a developing country purchaser. The term of the licence should, therefore, be at least as long as the term of the contract. If the contract is renewed, then the process should be simple for renewing the accompanying licence that has already been granted by the Commissioner of Patents. Limiting the possible term of a contract to only 2 years does not enable the producer to achieve economies of scale in producing lower-cost generic products, and provides less of a market incentive for generics to even negotiate such contracts. This would frustrate the objective of the bill.

Allowing a generic producer to obtain an authorization that matches the length of a contract, and allowing easy renewals of the authorization to match renewals in the contract, achieves the objectives of ensuring the system is streamlined and efficient. Furthermore, it reflects the mandate of enabling importing developing countries to make "effective use" of compulsory licensing to obtain lower-cost, generic medicines, which is the very objective of the WTO Decision of 30 August 2003 that Canada is supposed to implement with Bill C-9.

3. REPRESENTATIONS ON THE ISSUING OF A LICENCE

R_x&D requests that the bill be amended to give it an opportunity to make representations on the appropriateness of issuing a compulsory license and the terms of that licence. Its proposals in this regard are unnecessary and would have the effect of creating further red tape in the process that will render it even more unlikely to be effective, and defeat the purpose of a streamlined system.

With regard to specific points submitted by R_x&D:

- We agree that, in conformity with the TRIPS Agreement, Bill C-9 should require that, in the event of a compulsory licence issued by the Commissioner of Patents, the royalty should be determined on case-by-case basis. Our initial brief to the Committee proposed a system that would provide for this, but would preserve (a) the objective of keeping the price of these generic products low, since they are to be supplied in developing countries; and (b) would not allow a dispute over the royalty amount to hold up the process of issuing the licence and letting the licence-holder proceed with manufacturing and exporting the product in accordance with the contract it has negotiated.

- However, the additional proposals from Rx&D to make representations to the Commissioner of Patents are unnecessary and would create further opportunities for the patent holder to attempt to delay or block the process of issuing an authorization to the generic producer in order to preserve the market monopoly. Rx&D has also proposed provisions for terminating a compulsory license, beyond what is already in Bill C-9. Again, these provisions are unnecessary, and also invite litigation aimed at interfering with the efficient and effective use of this system. This is at odds with the objective of facilitating a speedy response to the needs of developing countries and enabling them to use compulsory licensing to establish *sustainable* and affordable sources of supply.

4. EXPORT PROVISION

The Canadian HIV/AIDS Legal Network agrees with the submission by the Canadian Generic Pharmaceutical Association, in its brief submitted to the Standing Committee on 26 February 2004, that Canadian patent law should not have extraterritorial effect.

Therefore, the Legal Network agrees that the *Patent Act* should be amended to include a provision, similar in some respects to s. 37(1) of the *Food and Drugs Act* as follows:

> *It shall not be an infringement of patent to use a patented invention without authorization of the patent holder to manufacture and export that invention to another country if either*
>
> > *(a) the invention is not patented in that country; or*
> >
> > *(b) the invention is patented in that country but a person other than the person holding the patent in that country is legally permitted to import and distribute the invention in that country.*

Such a provision in Canadian law would be permissible under **Article 30 of the TRIPS Agreement**. That Article states that:

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

It is open to Canada to determine, in its Patent Act, that one such "limited exception" permitted by TRIPS Article 30 is the proposed exception to patent rights in the case of exporting a generic pharmaceuticals to markets where the product is not patented or, if the product is patented, then

the appropriate legal steps have been taken to legally permit the importation into that country of a generic version (eg, a compulsory license has been issued by the competent authority).

Recall that **Article 1(1) of the TRIPS Agreement** states that WTO Member "shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

Furthermore, the World Health Organization has previously stated, during the negotiations that led to the WTO General Council Decision of 30 August 2003 (the basis for Bill C-9), that

> [T]he basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product.
>
> …the limited exception under Article 30 [of TRIPS] is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export patented medicines and other health technologies to address public health needs.[3]

[3] World Health Organization. "WTO Council for TRIPS: Statement by the representative of the World Health Organization", 17 September 2002.

5. SCHEDULE 1: LIMITED LIST OF PHARMACEUTICAL PRODUCTS

The Committee has heard from the Government that it is necessary to attach to Bill C-9 a list of pharmaceutical products for which a generic manufacturer can obtain a compulsory license for export. The Committee has also heard from numerous non-governmental organizations why such an approach is unnecessary and undesirable.

Fundamentally, such a limited list imposes a double standard on developing countries lacking their own pharmaceutical manufacturing capacity. No such limitation binds the scope of compulsory licensing in the case of any country that is fortunate enough to have its own domestic capacity to manufacture generic pharmaceuticals. The Doha Declaration of November 2001 expressly reiterated that countries are free to determine for themselves the grounds upon which to allow compulsory licensing, but recognized that countries lacking manufacturing capacity face difficulty in "making effective use" of this policy option.

The WTO Decision of 30 August 2003 was aimed at solving this problem – in other words, enabling countries lacking manufacturing capacity to make as effective use of compulsory licensing as countries that possess the capacity. That international consensus that was reached by all WTO Members was <u>not</u> restricted in scope to a particular list of pharmaceutical products. Canada should not unilaterally introduce such a restriction, undermining that consensus, in its domestic implementation of the WTO decision.

As the World Health Organization has pointed out, the WTO Decision of 30 August 2003 "covers all medicines". The WHO has also stated that "For the agreement to have the intended impact on public health, countries will need to review the full range of medicines required from multiple suppliers, including generic producers, when making purchasing decisions."[4]

We also wish to remind the Standing Committee of the comments made recently by the Prime Minister, on the occasion of his address to the World Economic Forum in Davos, Switzerland, in which he highlighted this legislative initiative as one of three examples where "the debate

[4] Statement of the World Health Organization on WTO access to medicines decision, 1 September 2003.

between political leaders must be lifted from the page – must go from pro forma to real commitment." The Prime Minister stated:

> "A second example where an intellectual leap is required – and where only political leadership can provide it – arises out of the collision between intellectual property rights and the need to provide low cost medicines to the poorest nations in the world. […]
>
> "**The question is: must every case of need, every new disease, spark a new debate?** Or can we have an open, political discussion that maps out general principles so that the world can react compassionately and comprehensively to new health crises?"[5]

The Prime Minister's remarks highlight that it is undesirable to take a disease-by-disease, need-by-need approach. Indeed the preferable approach, consistent with and supported by both the Doha Declaration and the August 30, 2003 decision from the WTO, is that the decision-making authority to decide when to use compulsory licensing to obtain cheaper products should rest with the country that is taking this step to address its own, self-determined "public health" needs.

[5] Notes for an address by Prime Minister Paul Martin, on the occasion of a session of the World Economic Forum, "The Future of Global Interdependence", Davos, Switzerland, January 23, 2004, at pages 1-3.

CONCLUSION

As the Treatment Action Campaign (TAC) and the AIDS Law Project (ALP) of South Africa have pointed out in their submission to the Standing Committee,[6] Canada's initiative of introducing Bill C-9 is important for three key reasons:

- First, as the developing countries that are currently producing generic medicines fully implement their obligations under the WTO's TRIPS Agreement, the supply of generic medicines will dwindle. This makes it all the more important for countries to change their domestic law to implement the WTO decision of 30 August 2003, because the greater the number of countries able and willing to produce generic medicines for export, the more likely these medicines will be available for import by countries that lack sufficient manufacturing capacity of their own.

- Second, the greater the number of generic products available, the greater the competition between producers. This promotes the financial sustainability of developing countries' treatment programmes because it keeps prices of medicines down.

- Third, as a G7 country, Canada's initiative can serve as an example that assists other countries in making full use of the public health flexibilities in the WTO patent rules, such as compulsory licensing. This is important, given the considerable pressure that has been, and continues to be, brought to bear on these countries to prevent them from actually using those flexibilities to which they are entitled under international law. In this regard, Canada's initiative would be damaging if it provided a model that actually *enhanced* patent protections and created an additional barrier to being able to effectively use compulsory licensing to foster the competition that brings medicine prices down.

For these reasons, it is important that, in implementing the August 2003 WTO Decision through Canada not add additional entitlements or restrictions that would undermine the effective use of compulsory licensing to foster the market competition that will bring down medicine prices.

[6] Treatment Action Campaign & AIDS Law Project. "Submission on Bill C-9 to Canada's Parliamentary Standing Committee", 26 February 2004.