Submission to the Standing Committee on Industry, Science and Technology

on

Proposed Government Amendments

to

Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act

Canadian HIV/AIDS Legal Network

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The Canadian HIV/AIDS Legal Network ("Legal Network") welcomes the introduction of the Government's proposed amendments to Bill C-9, and wishes to take this opportunity to provide its comments on those proposals.

1. Removal of the "right of first refusal" and prescribed time for seeking voluntary licence

The Legal Network commends the Government for its decision to eliminate the "right of first refusal" provisions. As we have submitted previously, these represented a fundamental flaw in the original text of Bill C-9, and we congratulate the Government for having responded to the concerns raised by numerous stakeholders in this regard.

Under the government's proposed amendments, all that is required before a compulsory licence issues is that the generic producer first seek, within the "prescribed time", a voluntary authorization from the patent-holder. As we have previously submitted, this is consistent with the requirement of TRIPS Article 31(b). We support this amendment.

The Legal Network recommends that the "prescribed time" that will be set out in the regulations must be a short period that will not lead to undue delay in implementing this system. We note that, in the August 30, 2003 Decision, WTO Members have already noted "the importance of a rapid response" to the needs of importing countries. The TRIPS Agreement simply requires that a "reasonable period of time" be provided for seeking a voluntary licence. It is open to Canada to define that period as it sees fit. We suggest a period of 15 days is reasonable.

> ***Recommendation:***
> *The "prescribed time" for seeking a voluntary licence from the patent-holder should not exceed 15 days.*

2. Need for fast-tracking in "emergency" situations and some other cases

The Legal Network notes that, under the TRIPS Agreement, the requirement to first seek a voluntary licence before a compulsory licence issues may be waived in the following circumstances:

- national emergency – Article 31(b)
- other circumstances of extreme urgency – Article 31(b)
- cases of public non-commercial use – Article 31(b)
- when the licence is issued to remedy a practice that has been determined by a judicial or administrative process to be anti-competitive – Article 31(k)

Neither the current text of Bill C-9 nor the Government's proposed amendments reflect this important flexibility in the TRIPS Agreement. This should be remedied by reflecting the waiver of the requirement to seek a voluntary licence in the circumstances listed above.

Recommendation:
Amend the proposed new section 21.04 to add a provision stating that: "The requirement set out in paragraph 21.04(3)(c)(i) does not apply if the country or WTO Member named in the application for the authorization has provided a notice in writing stating that it is faced with a national emergency or other circumstance of extreme urgency,that the product named in the application is for public non-commercial use, or that it seeks to import the product to remedy a practice that has been determined by a judicial or administrative process under its law to be anti-competitive."

3. Litigation over "commercial" agreements between generic companies and purchasers (proposed s. 21.17)

The Legal Network is disappointed to see that the Government proposes a brand new section inviting lengthy and vexatious litigation by patent holders over whether a generic company's agreement with a purchaser is "commercial" in nature. If the patent holder succeeds, it could lead to the generic company being stripped of its validly acquired licence.

The proposed section 21.17 sets out a process whereby the patent holder can seek a Federal Court order either terminating the generic producer's licence or ordering a higher royalty than is otherwise required under the Act and regulations. It can initiate this process merely by alleging that the generic producer's agreement allows it to charge a price above 25% of the patent holder's price in Canada. In order to avoid losing its licence, the generic would have to submit to a court-supervised audit and establish that the price it is charging does not exceed more than the direct supply cost plus 15%. Such a process compels disclosure of a generic producer's confidential business information to its competitor.

The proposed section 21.17 imposes caps on prices and profit margins for the generic producer, while specifying some vague criteria the Federal Court must apply in determining whether the generic producer's agreement is "commercial" in nature – as opposed to a "humanitarian" agreement, presumably. The vagueness of the criteria is further invitation to abusive litigation by patent-holders with a view to dissuading generic manufacturers from entering the field. History teaches us that this industry is a particularly litigious one, including the anti-competitive misuse of legal provisions by patent holders to block competition in the market.

The Legal Network's goal is not to secure any particular level of profits for generic pharmaceutical manufacturers, but rather to secure more affordable medicines for people in need,

as a matter of fundamental human rights. The Legal Network is committed to ensuring that government take a variety of measures to progressively realize the human right to the highest attainable standard of health for all. The Legal Network is also aware that the ultimate purpose of this legislation is to advance that objective through increasing accessing to medicines.

However, the success of this particular initiative depends on the engagement of for-profit, generic companies motivated by commercial purposes. Undermining incentives for those companies to enter the market could undermine the objective. It is, therefore, counter-intuitive to insist that commercial enterprises may lose their licence for agreements that are "commercial" in nature.

Finally, we are concerned that the scheme in the proposed section 21.17 is "TRIPS-plus" – that is, it exceeds anything required under the TRIPS Agreement or the WTO Decision of August 30, 2003. All that TRIPS Article 31 requires is that a patent holder have the right to seek judicial review or other independent review by a higher authority of the legal validity of the decision to issue a compulsory licence or the remuneration that is ordered to be paid. There is no requirement to impose caps on the prices or profit margins of the licence-holder or to enable litigation over such issues. Given that it is not necessary to include such provisions in Bill C-9, and the adverse effect it will likely have on the simple and straightforward operation of this system, it sets an undesirable global precedent to include them.

Recommendation:
Reject the proposed new section 21.17 in its entirety.

4. List of Pharmaceutical Products: Schedule 1

The Legal Network maintains that there should be no list of products in Bill C-9 at all. Neither the original TRIPS Agreement, nor the WTO General Council Decision of 30 August 2003, requires any such list. Rather, these documents refer simply to "any patented product, or product manufactured through a patented process, of the pharmaceutical sector" needed to address public health problems.

In addition, the Doha Declaration on the TRIPS Agreement and Public Health (November 2001) is not limited to only certain pharmaceutical products. In fact, it explicitly affirms that the concern is for "public health problems", that the TRIPS Agreement "should be interpreted and implemented in a manner" that supports a WTO Member's right to protect public health "and, in particular, to promote access to medicines for all." Furthermore, it explicitly affirms that each country has the freedom to determine for itself the grounds upon which to use compulsory licensing.

Furthermore, in the negotiations that led to the August 30, 2003 WTO Decision, proposals to limit the scope of the decision to certain diseases or certain medicines were flatly rejected. They do not form part of the international consensus that has been reached at the WTO.

Canada's legislation should not set a global precedent that would narrow what has already been agreed to at the WTO. Bill C-9 must clearly reflect the international consensus that access to more affordable generic medicines is the objective, not just specific products for specific diseases or conditions.

Recommendation:
Delete Schedule 1.

5. Importing countries: restricting eligibility to "emergencies" only (proposed s. 21.03)

We welcome the Government's decision to expand the list of eligible importing countries to include many developing countries that are not WTO Members, in recognition of the principle that access to more affordable medicines should not depend upon whether one's country of residence belongs to the WTO.

However, we question why the Government is proposing that, in order to be added as an eligible importing country, a developing country otherwise eligible for official development assistance

- will have to declare that it is faced with a national emergency or other circumstances of extreme urgency, and
- can only be added to the schedule for the purposes of importing a specific product, and in a specific quantity, that it states is needed to deal with that urgent situation.

This "emergency-by-emergency, product-by-product" approach to letting non-WTO developing countries import from Canada is neither ethical nor sound from a public health perspective. Developing countries which belong to the WTO do not face the "emergency" threshold, nor must they must they be approved as eligible importers on a medicine-by-medicine basis. There is no reason to impose a higher standard on non-WTO developing countries.

Recommendation:
Delete sub-paragraphs (A) and (B) of the proposed new section 21.03(1)(d)(ii).

We also note that, throughout the bill, the Government proposes to require that multiple Ministers make a recommendation to Cabinet before a country may be added to the relevant schedule of countries eligible to import from Canada. This is unnecessary red tape and should be rejected.

Recommendation:
Remove all references to requiring multiple Ministerial recommendations in order for Cabinet to be able to add a country to the relevant schedule as eligible to import from Canada.

6. Requirement that importing country must agree to not allow use of product for "commercial purposes" (proposed additions to s. 21.03 and s. 21.14)

With respect to both least-developed and developing countries that may be added to the relevant Schedules under Bill C-9, the Government is proposing that the country may be added by Cabinet only if the country provides a notice in writing stating that it agrees that an imported product "will not be used for commercial purposes." Under the Government's proposed amendments, if the country permits the product to be used for commercial purposes, the compulsory licence that has been issued to the exporting producer may be terminated by the Federal Court.

It is not clear what activity will be captured by this prohibition on using the product "for commercial purposes." In many settings, distribution of the imported generic product will necessarily happen not only through public sector hospitals, clinics and other institutions, but also through other distribution channels such as private pharmacies, which are clearly "commercial" actors. If the Government's proposed prohibition on allowing the use of imported medicines for commercial purposes interfered with such distribution, then it would seriously undermine the effectiveness of the initiative. The Government should clarify the intent behind such provisions.

In any event, such a provision in Bill C-9 is not in any way required by the August 30, 2003 WTO Decision the bill is meant to implement, nor is it required under the TRIPS Agreement. It is "TRIPS-plus" and should be rejected.

Recommendation:
Reject all references to a country agreeing that the product will not be used for commercial purposes.

7. Uncertainty regarding royalties (proposed s. 21.08)

The Government proposes to amend the provisions setting the royalty rate, by removing the fixed rate of 2% of the value of the product exported under the licence and instead leaving the issue of the royalty to be determined in a manner "prescribed" by regulations. This creates uncertainty where none existed and, in that respect, the proposed amendment is undesirable.

We do not object to some variation being permitted in the royalty rate, but stress that it must be capped overall at some figure (we have previously proposed 4%) and must be predictable. This should be reflected in the regulations that will govern how the royalty is calculated. Those regulations must be clear and straightforward, allowing all parties to calculate, with reasonable certainty, what the royalty rate would be in any given instance.

The Government's proposed amendment would only afford the patent holder an opportunity to apply to the Federal Court to seek a *higher* royalty. An equivalent provision that would allow a generic producer to seek a court order for a *lower* royalty should be added if this section is retained.

The Federal Court is given the authority to order a royalty rate higher than what would be required under the regulations if it is satisfied that the usual royalty is inadequate. But one of the criteria to be applied by the Court in making that assessment is not clear. What is meant by "the economic value of the use of the invention or inventions to the country or WTO Member"? How will this be calculated? The lack of clarity here is a further invitation to litigation by patent-holders to dissuade generic producers' participation in this initiative.

Recommendations:
Reject the proposed section 21.08(7)(a).
Add provisions to section 21.08 allowing a generic producer to seek a court order lowering the royalty otherwise payable.

8. Two year limit on licences (proposed s. 21.09)

The Government has retained its original cap of a maximum 2-year term on any compulsory licence that is issued. This is an arbitrary restriction and makes it more difficult for a purchaser to negotiate a longer-term contract with a Canadian generic supplier, thereby creating less of an incentive for participation by these producers and hindering the economies of scale – and therefore savings to the purchaser – that could be achieved with longer-term, more secure contracts.

There is nothing in either the TRIPS Agreement or the WTO Decision of August 30, 2003 that requires any such time limit on the term of a compulsory licence. This is a "TRIPS-plus" provision that will have an adverse effect on the sustainability and workability of this system, as well as setting a poor global precedent on this point. It should be removed.

Recommendation:
Delete the 2-year limitation on the term of an authorization granted by the Commissioner. Allow the Commissioner to issue the authorization to coincide with the length of the contract on which the application is based.

9. NGO procurement of medicines

The Legal Network understands the Government's amendment to section 21.04 will remove the restriction that only a government or "agent of government" may procure medicines from a Canadian generic producer. The new language proposed refers to the "person or entity to which the product is to be sold". In our view, this language would allow a non-governmental organization (NGO) to procure medicines from a generic producer (assuming the NGO was legally entitled to import and distribute in the country where it is operating).

We welcome this amendment and commend the government for having addressed this concern about exclusion of NGO purchasers.