CANADIAN HIV•AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH•SIDA

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Standing Committee on Industry, Science and Technology
House of Commons
180 Wellington Street
671, Wellington Building
Ottawa, Ontario K1A 0A6

Dear Members of the Standing Committee:

Re: Bill C-9 and the issue of NGO procurement of Canadian-made generic pharmaceuticals

On behalf of the Canadian HIV/AIDS Legal Network, let me thank you again for the opportunity to appear before you and to provide you with submissions regarding Bill C-9. As was requested by the Committee when we appeared before you on February 26, 2004, we have provided the Committee with our supplementary submissions regarding the alternatives to the "right of refusal" that had been proposed to the Committee. We trust you found those additional submissions helpful and that they have clearly explained why the alternative proposal from Canada's Research-based Pharmaceutical Companies (R_x&D) is not substantially different from, and represents no improvement over, the right of refusal as it currently appears in Bill C-9.

However, discussions at subsequent Committee meetings have indicated that Committee members are under a fundamental misapprehension with regard to another key aspect of our submission – namely, the concern that **Bill C-9 excludes the possibility of NGOs procuring lower-cost pharmaceutical products** from Canadian generic producers.

We are concerned that Committee members have an incorrect impression of the concern that NGOs have raised. **Whether the Committee ultimately accepts or rejects our proposals on this point, it is important that our proposals be at least properly understood so that the Committee's deliberations actually deal with the proposal in question, rather than with imagined requests that we have not made.**

We have, therefore, taken the step of submitting this additional comment in order to clarify this point for Committee members.

NGOs as purchasers of pharmaceutical products

It appears that some Committee members believe that NGOs have suggested that Bill C-9 should give them the right to grant themselves compulsory licenses and then seek to purchase Canadian-made generic products, and that NGOs have disregarded any requirement for involvement by the governments of the exporting or importing countries. However, this is not an accurate perception of our proposal, so we wish to clarify this point.

Rather, all we have suggested is that, if it is legally permissible for an NGO to import a generic version of a particular product into a developing country (e.g., for use in its treatment programmes), then there is no reason why it should not be able to contract directly with a Canadian generic producer, which contract should be an acceptable basis for the Canadian generic producer to seek the requisite compulsory license under Bill C-9.

After all, NGOs currently have many contracts with pharmaceutical companies to buy their products – with brand-name companies (in the case where a product is still patented) and generic pharmaceutical companies (in the case where either a product has never been patented or the patent has expired). There is no reason why an NGO and a generic company cannot sign contracts for the sale and purchase of medicines. They do so regularly already.

By way of example, consider that an organization such as Médecins Sans Frontières wishes to import a generic anti-retroviral drug to treat people living with HIV/AIDS into the country of South Africa. If that medicine is patented in South Africa, it must obtain a compulsory license authorizing it to import the medicine. The compulsory licence needs to be issued by the appropriate legal authority, as defined in South African law, which need not be the executive branch of government. If such a licence is issued, then MSF has the legal permission to import a generic version of that product and distribute it in South Africa. There is no reason why Canada's Bill C-9 should not recognize this valid legal authority.

Yet as Bill C-9 is currently worded, it only allows a contract between a Canadian generic producer and a government or "agent of government" to serve as the basis for a request for a compulsory licence to Canada's Commissioner of Patents. This is an unnecessary restriction, since it fails to recognize the situation in which an NGO has already obtained the necessary legal authorization to import the product in the developing country.

We adverted to this point in our original submission to the Committee (at page 23). Furthermore, as we have noted in Appendix I (at pp. 32-33) of our original submissions to the Committee, it is important to appreciate that, under the law of an importing country, there may be a variety of authorities, independent of the executive branch of government, that are competent to grant a compulsory license. Canada itself is an example: under our Patent Act, the independent Commissioner of Patents has this authority under the Patent Act. If a person obtains a compulsory license under Canadian law from the Commissioner of Patents, no further action is required to confer on that person the legal right to deal with that patented product in accordance with the terms and conditions of the licence. The same situation obtains in numerous other countries that would seek to import generic medicines from producers such as Canadian generic manufacturers.

Furthermore, it should be noted that all that is required under the WTO General Council Decision of August 30, 2003 is that the government of the country into which the generic product is imported provide notification in writing that either the product is not patented in that country or that, if it is patented, a compulsory licence has been issued by a competent authority in that country. The August 30, 2003 WTO decision does not say that only the government may issue a compulsory license; the requirement of government action is merely one of notification confirming the fact that a licence has been issued on a specific product.

WTO website and posting requirements under the August 30, 2003 decision

The Canadian HIV/AIDS Legal Network also wishes to offer some additional comments in response to some questions that were raised recently by Committee members.

It has been suggested by R_x&D, in its brief submitted to the Committee on February 26, 2004, that Bill C-9 should require any country wishing to purchase and import cheaper generic medicines to post its tender on a WTO website. In response, it has been pointed out to the Committee that no such website presently exists. Nor has any such requirement been negotiated and agreed between WTO members in the decision of August 30, 2003. This proposal is completely foreign to the system negotiated in the August 30, 2003 decision.

However, there appears to be a misunderstanding on the part of the Committee regarding the references to websites in the August 30th decision. It should be clarified that the website referred to in **paragraph 2(c)** of the August 30th decision is a page on the WTO website on which an exporting country must post its notification the WTO Council for TRIPS when it has granted a compulsory license. As stated in that paragraph, the exporting country must post details about the actual product(s) being exported, the quantities being exported, the destination country, etc.

(That web page can be found at http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm in English and at http://www.wto.org/french/tratop_f/trips_f/public_health_f.htm in French.)

This is one of the measures aimed at preventing diversion of the generic products that are produced under this system. It has nothing to do, however, with any suggested requirement that an importing country post its tender for any pharmaceutical product(s) on a WTO website. The R_x&D proposal for such a process of posting bids on a WTO website has no basis in the TRIPS Agreement, the Doha Declaration from November 2001 or the Decision of August 30, 2003.

We are pleased to discuss any of the above points, or others raised in our previous submissions or during the Committee hearings, at your convenience.

Sincerely,

Richard Elliott
Director, Legal Research & Policy