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, ON
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Dear Members of the Standing Committee:

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

I write to follow up on our previous submissions to the Standing Committee regarding Bill C-9, Canada's laudable initiative to implement the WTO General Council Decision of August 30, 2003 to enable countries lacking sufficient pharmaceutical manufacturing capacity to "make effective use" of compulsory licensing to obtain lower cost generic pharmaceutical products manufactured in Canada.

As you may know, the World Health Organization is currently preparing a guidance document aimed at explaining how countries who wish to use the system set out in the August 30th Decision, either as importers or exporters, may go about doing so. To that end, it convened yesterday, March 25th, in New York City, in collaboration with the Ford Foundation, an Expert Consultation on TRIPS and the implementation of the August 30th Decision. At that consultation, there was considerable discussion of Bill C-9, as Canada is the country that, to date, has the greatest amount of experience in trying to implement the August 30th decision, and the Canadian initiative therefore offers a variety of lessons to be learned.

Therefore, I write to share you with some of the key points arising from that Expert Consultation, as this information may be of use to you in your current deliberations regarding several important outstanding issues with possible amendments to Bill C-9.

In attendance at the WHO consultation were a variety of the world's leading experts on the question of TRIPS and access to medicines. These included: the principal expert on TRIPS and public health from the WTO Secretariat; the Ambassador of the Mission of Zimbabwe to the UN and WTO (who played a key role, on behalf of the Africa Group, in putting this issue on the WTO agenda and in the discussion that led to both the Doha Declaration of November 2001 and the August 30th General Council Decision); experts from the World Intellectual Property Organization, the UN Development Programme, the Joint UN Programme on HIV/AIDS, and the World Health Organization; representatives of non-governmental organizations, including Médecins Sans Frontières and the Ethical Globalization Initiative headed by Dr. Mary Robinson, former UN High Commissioner for Human Rights; and, finally, leading academic medical and legal experts, including Professor Jerome Reichman of Duke University, whom I understand is among the legal experts consulted by the Government of Canada in the course of its current deliberations. The Government of Canada was represented by Health Canada. The Canadian HIV/AIDS Legal Network also attended the meeting.

There was considerable discussion of Bill C-9 at the Expert Consultation, and in particular there was a lengthy discussion regarding the issue of the "right of first refusal" and various alternatives thereto that have been proposed by different stakeholders. For the benefit of the Committee, I draw to your attention a number of key observations arising from the discussions:

(1) "Right of first refusal" and various proposed alternatives

- There was a consensus that neither TRIPS (including Article 31(b)) nor the August 30th Decision mandate any "right of first refusal", as it appears in the current text of Bill C-9, that would require giving the patentee the right to assume a contract that has been negotiated by a generic producer with a purchaser.

- Similarly, there was a consensus that neither TRIPS nor the August 30th Decision mandate a system, such as that proposed by Canada's Research-Based Pharmaceutical Companies under the label "equal opportunity to supply", that would require, of either a generic producer or a purchasing country or organization, that they notify the patentee of current negotiations over the terms of a potential contract to supply the product in question.

- There was a consensus that TRIPS Article 31(b) only requires that, in the absence of an emergency situation, other circumstances of extreme urgency, or in the case of public non-commercial use or to remedy anti-competitive practices, a request be first made to a patentee <u>for a voluntary licence</u>, before steps could be taken to have a compulsory licence issued. There was agreement that no additional entitlements or procedural steps are required by TRIPS Article 31(b), and that TRIPS Article 31(b) does not require any other form of "notification" to patentees other than the request for a voluntary licence on reasonable terms and conditions. Professor Reichman, for example, was perplexed as to why Canada, or any other potential exporting country, would do anything other than simply follow the language and requirements of Article 31(b) or would add further requirements. He also questioned why any country would consider provisions beyond those required by Article 31(b), when such an approach to implementing the August 30th decision would invite possible criticism at the Council for TRIPS which, under the terms of the Decision, is the forum identified for any WTO Member to bring forward concerns about the implementation of the Decision.

- There was agreement that the August 30th Decision does not require an importing country to post a public tender, whether on a WTO website or elsewhere, soliciting bids from would-be suppliers of a pharmaceutical product or products. (Countries may, of course, choose to proceed in this fashion, but it is not legally mandated by either TRIPS or the August 30th Decision. The Canadian HIV/AIDS Legal Network notes that this issue was raised before the Standing Committee earlier this month. In response, it has been pointed out that WTO Members have not negotiated any such obligation nor have they agreed that the website "notifications" referred to in the August 30th Decision amount to a limitation that Members may only procure medicines through a public notification process, whether website-based or otherwise.)

- There was agreement that, under TRIPS and the August 30th Decision, there is no requirement, before initiating the process of seeking a voluntary or compulsory licence, that a purchaser first request that the patentee reduce its price on a patented products. (Again, countries may, as a matter of practice, regularly do so, in the hopes of obtaining the product most simply and quickly, at a reasonable price, from the supplier that is, by virtue of being the patent-holder, the current sole supplier in the market. But there is no legal requirement, under TRIPS or the August 30th Decision, to take such a step; creating such an additional requirement in Bill C-9 would amount to a return, in essence, to a legally mandated "right of first refusal" for patentees and would set a new "TRIPS-plus" precedent that would be undesirable given its subsequent international implications.)

(2) List of pharmaceutical products

- There was agreement among participants in the Expert Consultation that the August 30th Decision is not limited to only certain pharmaceutical products beyond the description that they be for "public health needs". There was agreement that the determination of need is made by the importing country and this determination is not subject to approval by the WTO.

(3) Duration of compulsory licenses in exporting country

- There was no support for the approach, currently found in Bill C-9, on arbitrarily limiting the duration of a compulsory license to a maximum of 2 years. There was some, albeit limited, support for the view that the duration of a compulsory license should at least correlate to the term of the particular contract that a generic producer has negotiated to supply a particular product to a developing country. (I note that this is a position that various Canadian NGOs have put forward to the Standing Committee.)

- However, there was much more support, from all quarters, for the idea that a compulsory license issued in an exporting country should be either for the remaining term of the patent(s) in question or should be an open-ended licence, both of which would be activated, through simple administrative procedures, in response to ongoing notification of needs by an importing country, thereby better achieving the objectives of enabling importing countries to make effective use of compulsory licensing and of enabling a rapid response by Canadian suppliers of generic pharmaceuticals.

As the Committee continues its deliberations regarding several key outstanding issues in the language of Bill C-9, in the light of submissions that have been made by various stakeholders, we trust the above information will be useful to you. Following the Expert Consultation it has just held, the World Health Organization anticipates producing its guidance document on the best, most public-health friendly implementation of the August 30th Decision in time for the next meeting of the WTO Council for TRIPS, in June 2004. It is expected that, at that meeting, this issue will receive further attention, along with the state of progress by various countries in their efforts to implement the Decision.

Please be assured that Canadian civil society organizations remain, as always, willing to work with the Government of Canada and all parties in the House of Commons to secure the passage of legislation that is a full and faithful implementation of the international consensus that is embodied in the August 30th Decision. As we have maintained consistently from the beginning of this process, we are eager to see Canada show true leadership internationally in responding to the global HIV/AIDS pandemic and other health challenges, but do not wish to see this widely-acclaimed initiative codify unnecessary "TRIPS-plus" provisions of any sort, given the unfortunate international precedent such a development would set, with all the adverse consequences down the road for overall efforts to increase access to medicines for people in the developing world.

We would welcome the opportunity to support passage of a bill that places concern for the health of the world's poor front and centre, as a matter of fundamental human rights that takes priority over demands for additional, unnecessary privileges for the holders of medicine patents. We have communicated our views on these matters to all parties in the House of Commons and will continue to urge all Members of Parliament to avoid playing politics with people's lives. We hope that, in the final analysis, those efforts will complement a desire by the Government of Canada to take a bold, principled position and demonstrate the leadership that is expected of Canada as a result of having launched this initiative.

Please do not hesitate to contact us if we can be of further assistance or provide you with additional information regarding this matter.

Respectfully yours,

Richard Elliott
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