Reforming Canada's Access to Medicines Regime (CAMR):
Bill C-393 – Finding the Expeditious Solution

Conclusions of an International Expert Consultation
convened by the UN Development Programme and
the Canadian HIV/AIDS Legal Network

New York, February 18, 2010

INTRODUCTION

In February 2010, a varied group of legal experts on intellectual property law and access to medicines from North America, Africa and Europe were brought together at the UNDP headquarters in New York City to discuss *inter alia* whether the reforms proposed to Canada's Access to Medicines Regime (CAMR) by Bill C-393 are compliant with the applicable provisions of WTO law, including:

- the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS");
- the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") adopted on 14 November 2001 by the WTO Ministerial Council; and
- the WTO General Council Decision of 30 August 2003 on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", and the accompanying statement by the Chairperson of the General Council ("2003 WTO Decision").

The anticipated outcome of the meeting was two-fold:

- to assess claims by critics that Bill C-393's proposed reforms are not consistent with Canada's obligations as a WTO Member; and
- *if necessary*, to propose amendments to Bill C-393 to ensure compliance with Canada's obligations under TRIPS.

Critics of Bill C-393 have focused their claims of non-compliance with WTO obligations on several key aspects of the Bill. The experts at the international consultation therefore focused their attention on those elements. This report summarizes the key conclusions and recommendations from the consultation.

BILL C-393 AND TRIPS-COMPLIANCE: KEY ISSUES

ISSUE #1 Eliminating requirement to identify a specific importing country as precondition of issuing a compulsory licence (i.e., the sequencing issue)

Current law

Under the current CAMR, no application for a compulsory licence may be made, and no compulsory licence may be issued by the Commissioner, unless and until a specific importing country is identified. This arises out of the operation of the following provisions in the *Patent Act*:

- Section 21.04(2)(e) requires that, in applying for a compulsory licence, a generic manufacturer must set out "the name of the country or WTO Member to which the pharmaceutical product is to be exported".

- Section 21.04(3)(c) states that the Commissioner may only issue a compulsory licence if, among other requirements, the generic manufacturer provides the Commissioner with a solemn or statutory declaration stating that, at least 30 days before filing the application for a compulsory licence,

    - the generic manufacturer had sought in writing from the patent-holder(s) a voluntary licence(s) to make and sell the pharmaceutical product "for export to the country or WTO Member named in the application [to the Commissioner] on reasonable terms and conditions and that such efforts have not been successful; and
    - in that written request for a voluntary licence, the generic manufacturer provided the patent-holder(s) with, among other things, the name of the country or WTO Member to which it wishes to export the product.

It was noted at the consultation that this requirement of identifying a specific country in advance of pursuing a licence under CAMR – whether a voluntary one initially, or subsequently a compulsory one if efforts to secure a voluntary one fail – had resulted in extensive delays with the experience to date of attempting to use CAMR by Médecins Sans Frontières (MSF) and Apotex. Those efforts were initiated in early 2005 and ultimately abandoned by MSF in 2006. Without the ability to name a specific importing country, Apotex was unable to satisfy the CAMR requirements of (i) seeking, for at least 30 days, a voluntary licence to supply said country from the patent-holders, and then (ii) applying for a compulsory licence. This situation persisted until July 2007, when Rwanda notified the WTO's Council for TRIPS of its intent to use the 2003 WTO Decision and CAMR, thanks in part to intervention by the Clinton Foundation HIV/AIDS Initiative. No other such notification has been made to date by any country.

Proposed reforms

Bill C-393 would eliminate the requirement to identify a specific country as a pre-condition of pursuing and obtaining a compulsory licence under CAMR. It does so by:

- deleting the requirement in *Patent Act* s. 21.04(3) that seeking a voluntary licence from the patent-holder(s) must be done for a 30-day period which only starts to run once, among other things, the generic manufacturer names a specific importing country to which it wishes to export;
- deleting the requirement in *Patent Act* s. 21.04(2) that the application to the Commissioner of Patents for a compulsory licence include the name of a specific country to which exports would be authorized under the licence; and
- amending *Patent Act* s. 21.04(1) such that the Commissioner of Patents issues a compulsory licence that is not restricted to authorizing exports to a specific country, named in advance in the generic manufacturer's application, but rather to any of the eligible countries listed in the Schedule.

Working group's assessment

The working group agreed that no provision in either the 2003 WTO Decision or TRIPS requires that an importing country be identified before a compulsory licence is issued in the exporting country. The 2003 WTO Decision – specifically paragraphs 2(a) and 2(c) – do impose some requirements on both the importing and exporting country to file notifications with the WTO's Council for TRIPS, but they do not require an exporting country such as Canada to impose the sequence of events currently set out in CAMR. The amendment proposed in Bill C-393, to remove the current CAMR requirement that the importing country be named in the request for a voluntary licence and subsequently the application for a compulsory licence, complies with WTO requirements.

Working group's conclusion

Bill C-393's amendments on this point are WTO-compliant.

ISSUE #2 Single licence authorizing exports to multiple countries

Current law

Under the current CAMR - specifically *Patent Act*, s. 21.04(2)(e) – in applying for a compulsory licence, a generic manufacturer must set out "the name of the country or WTO Member to which the pharmaceutical product is to be exported". In addition, pursuant to *Patent Act* s. 21.04(1), the licence issued by the Commissioner of Patents authorizes the generic manufacturer to use the patented invention only for purpose of export "to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application." Finally, s. 21.04(3)(c) also notes that, before the Commissioner may issue a compulsory licence, the generic manufacturer must establish that it has attempted to obtain from the patent-holder(s) a voluntary licence to export the product "to the country or WTO Member named in the application."

All of these provisions in the current CAMR are worded in the singular in referring to the eligible importing country or WTO Member. The accompanying forms for applying for a compulsory licence, and for the licence issued by the Commissioner, are set out in the regulations that accompany the *Patent Act*. These are also worded in the singular, tracking the language of the *Patent Act*.

Proposed reforms

Bill C-393 seeks to:

- amend s. 21.04(2) to remove the apparent requirement to name only a single country in the application for a compulsory licence; and instead
- amend s. 21.04(1) to authorize exports to any of the countries that are listed in the Schedule (condensed to a single list by Bill C-393) as eligible importing countries.

Working group's assessment

There was agreement among the expert working group that the reforms proposed by Bill C-393 do not contravene the 2003 WTO Decision or any provisions in TRIPS. There is no requirement in WTO provisions that a compulsory licence that is issued under a regime such as CAMR be limited to authorizing exports to just a single importing country. In fact, the working group pointed out that Bill C-393 itself could be improved by making it even clearer, within its amendment to the current section of the *Patent Act*, that a single compulsory licence can be issued that authorizes exports to multiple countries.

In particular, the working group specifically noted that paragraph 2 of the 2003 WTO Decision itself refers specifically to "eligible importing Member(s)" in several places, clearly phrased in the plural. The introductory portion of paragraph 2 refers to "the grant by it [the exporting

Member] of a compulsory licence" for purposes of producing "a pharmaceutical product(s)" and the export of that product to "an eligible importing Member(s)". Paragraph 2(b) states that "the compulsory licence" issued by the exporting Member shall contain the following conditions:

> (i) the amount necessary to meet the needs of the "eligible importing Member(s) may be manufactured under the licence and the entirety of this product shall be exported to the Member(s) in question"
>
> (ii) "products produced under the licence shall be clearly identified etc…"'

Paragraph (2)(c) of the 2003 Decision also states that the exporting country's notification to the TRIPS Council must include such information as "the product(s) for which the licence has been granted" and "the country(ies) to which the product(s) is(are) to be supplied and the duration of the licence."

Therefore, the language of the 2003 WTO Decision itself indicates that it is permissible to list multiple countries in a single licence.

The working group did stress that, to provide comfort to legislators, amendments to CAMR should be very clear in ensuring that compulsory licences issued should authorize exports only to countries identified in the 2003 WTO Decision as "eligible importing countries". The 2003 WTO Decision, paragraph 1(b) defines this category as follows:

> *"eligible importing country" means any least-developed country Member and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it is being understood that a member may notify at any time that it will use the system as a whole or in limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of non-commercial use.*

The 2003 WTO Decision also explicitly states that there are a number of high-income, developed WTO Members that will not use the Decision as importers,[1] and the accompanying Chairperson's statement notes on the record that numerous other WTO Members have stated that if they used the system, *it would be in no more than situations of national emergency or other circumstances of extreme urgency*.[2] The working group noted that, roughly reflecting the

[1] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

[2] Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates. In addition, the following countries have indicated that, until their accession to the European Union, they would only use the system as importers in cases of national emergency or other circumstances of extreme urgency, and that, following EU accession, they would opt out of the system entirely as importers: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

2003 WTO Decision adopted by all WTO Members, the existing CAMR already defines the following as eligible importing countries:

- in Schedule 2: existing UN-recognized least-developed countries (LDCs) and any such LDC not currently on the list that provides the requisite notification to the TRIPS Council (or directly to Canada in the case of a non-WTO Member);
- in Schedule 3: other non-LDC countries that belong to the WTO and that have not voluntarily restricted themselves to using the 2003 WTO Decision only in cases of "national emergency or other circumstances of extreme urgency"; and
- in Schedule 4: (i) any other WTO Members that have voluntarily restricted themselves to using the mechanism only in cases of "national emergency or other circumstances of extreme urgency", as well as (ii) any developing countries that are named on the OECD's list of countries eligible for official development assistance, that do not belong to the WTO and that agree in writing to only use such the 2003 WTO Decision to deal with emergencies.

The working group made the following additional observations:

- The 2003 WTO Decision is silent as to criteria for eligibility of non-WTO Members as importers. Therefore, there is nothing in the WTO Decision that prevents Canada from making CAMR available to benefit non-WTO countries. The existing CAMR already explicitly includes some non-WTO Members who are LDCs as eligible importing countries, and it also allows that other developing countries who are not WTO Members could also potentially be eligible importers of generic pharmaceutical products under CAMR.
- However, in the case of countries which are not LDCs but which are eligible for official development assistance under the OECD list, the current CAMR imposes some restrictions on countries which are *not* WTO Members that are not imposed by the 2003 WTO Decision on developing countries that *are* WTO Members – such as the limitation that non-WTO developing countries may only be considered eligible importing countries in cases of declaring an emergency.
- Given the silence of the 2003 WTO Decision on criteria for eligibility of non-WTO Members as eligible importers, it cannot be said that such additional restrictions in CAMR on non-WTO developing countries are required by the WTO Decision.
- In the case of developing countries other than LDCs, Bill C-393 seeks to eliminate the distinction between WTO Members and non-WTO Members by simplifying the structure of the current country schedules and combining them into a single Schedule of eligible importing countries under CAMR that would include both:
    - any country recognized by the UN as a least-developed country; and
    - any country named on the OECD's list of countries eligible for official development assistance.

Bearing in mind the wording of the WTO Decision (paragraph 1(b)) by which all WTO Members are bound, as well as the decision already made by Canada in the current CAMR to recognize non-WTO Members as eligible importing countries – albeit under some restrictions not applied to WTO Members – it is unnecessary for the Canadian legislation to further limit the scope of eligible importing countries. However, the language in Bill C-393 could be clearer in referring to "eligible importing countries".

Working group's recommendation

The reforms proposed in Bill C-393 are generally WTO-compliant. However, it was recommended at the meeting that in order to more closely track the language of the 2003 WTO Decision, and to make it clear that a compulsory licence issued under CAMR authorized exports to any eligible country identified in the law, Bill C-393, s. 4 should be amended so that, upon its adoption, the final version of *Patent Act*ion s. 21.04(1)(c) (regarding the scope of the compulsory licence issued by the Commissioner) would read as follows:

> *s. 21.04(1)(c): "sell the product or products for export to ~~a~~ any eligible importing country that is listed in the Schedule."*

ISSUE 3 Quantity of product authorized for export by a compulsory licence

Current law

Under the current CAMR, a compulsory licence authorizes export only of a limited and fixed quantity of a given pharmaceutical product (to a single recipient country). This arises as a result of the following sections of the current *Patent Act*:

- Section 21.04(2)(c) states that, in its application to the Commissioner of Patents for a compulsory licence, the generic manufacturer must set out "the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization."
- Section 21.04(3)(c) states that the Commissioner may only issue a compulsory licence if, among other requirements, in seeking in writing a voluntary licence from the patent-holder(s), the generic manufacturer has identified this same quantity of the product as the "maximum quantity" specified in the application for a compulsory licence.
- Section 21.04(3)(d) states that the Commissioner may only issue a compulsory licence if, among other requirements, the generic manufacturer provides a copy of the notification filed by the importing country with the WTO TRIPS Council (or Canada, in the case where the importing country is not a WTO Member), setting out not only the name of the pharmaceutical product but also "the quantity of that product, needed by the WTO Member [or country]".
- Section 21.05(2) states that the quantity of the product authorized for export in a compulsory licence may not be more than the lesser of either (a) the "maximum quantity" set out in the application for the licence or (b) the quantity set out in the notice filed by the importing country with the TRIPS Council (or directly with Canada, in the case of an importing country that is not a WTO Member).

Proposed reforms

Bill C-393 would remove the requirement in CAMR that the "maximum quantity" must be set out in the application for an authorization of a compulsory licence to export and would not impose a fixed, pre-determined cap on the specific number of units of a pharmaceutical product that could be exported under the authority of the compulsory licence.

Working group's assessment

The working group noted that:

- There is no requirement under TRIPS or the 2003 WTO Decision to impose an absolute, fixed limit on the quantity of the product that may be exported under a compulsory licence. CAMR's current requirement that an applicant for a compulsory licence specify a "maximum" quantity of the product to be authorized for export under the licence is

not a provision required under TRIPS or the WTO Decision, and there is no use of the term "maximum quantity" in the WTO Decision or TRIPS.

- The expert working group agreed that the any requirement to impose a specified numerical "maximum" quantity of the product that could be exported under a compulsory licence unnecessarily limits the effectiveness of the 2003 WTO Decision. A mechanism implementing the WTO Decision should be able to easily accommodate changing needs of importing countries for medicines.

- The 2003 WTO Decision – in paragraphs 2(a)(i) and 2(b)(i) – does impose the following requirements:
    - Eligible importing countries must notify the TRIPS Council of the "expected quantities of the product(s) needed."
    - Exporting countries (e.g., Canada) must ensure that a compulsory licence issued under CAMR contains the condition that: "only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS".

The working group discussed that, under the amendments proposed in Bill C-393, there is not an explicit limit on the quantity that may be exported under a compulsory licence. Instead, the control on quantity exported arises from the interplay of the following factors:

- As a practical business reality, a generic manufacturer will not export a product unless it has a purchaser (in an eligible importing country) with whom it has signed a contract, which will certainly specify some quantity of the product.
- Bill C-393 preserves (in *Patent Act* s. 21.16) the requirement that a generic manufacturer must disclose the contracts it has negotiated with developing country purchasers within 15 days and may not export any product until it has done this disclosure. (Bill C-393 also preserves the provision in *Patent Act* s. 21.14(1)(e) that a court may terminate a compulsory licence if the generic manufacturer fails to comply with this requirement.)
- The disclosure of the quantities purchased by eligible importing countries, pursuant to their contracts with generic manufacturers, serves to identify the needs of importing countries.
- In any event, importing countries are required to notify the TRIPS Council of their "expected needs"

Working group's recommendations

To ensure greater clarity in regulating the quantity of a pharmaceutical product exported under a compulsory licence, as well as to ensure clearer conformity with the requirements of TRIPS

and the 2003 WTO Decision, while ensuring that compulsory licences issued under CAMR are flexible enough to respond to the changing needs of eligible importing countries, the working group recommended two minor amendments to Bill C-393:

1. *Patent Act* s. 21.06 should read, after amendment, as follows:

   21.06 *(1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the eligible importing country or countries to which it is to be exported, the quantity of the product being exported to each country and the distinguishing features of the product, and of its label and packaging.*[3]

2. Bill C-393 should include an additional clause that would add to the *Patent Act* (likely in s. 21.05), or in the regulations that set out the form of a compulsory licence issued by the Commissioner of Patents, the following as a standard condition of any compulsory licence issued under CAMR:

   The holder of an authorization is authorized to export the product to the extent necessary to meet the needs of eligible importing countries, as notified to the TRIPS Council in writing from time to time, if the importing country is a WTO Member, or to the Government of Canada through diplomatic channels, if the country is not a WTO Member.

In the working group's view, these amendments would provide another means of ensuring public disclosure of the quantities being exported to individual eligible importing countries are reasonable in relation to those importing countries' "expected quantities" as notified to the TRIPS Council (or the Government of Canada, as the case may be). This would also strengthen the anti-diversion measures in Bill C-393.

[3] Section 21.14(1)(b), which is not amended by Bill C-393, states that a compulsory licence may be terminated by the Federal Court if the licence-holder fails to disclose on the website the information that is required by s. 21.06.

ISSUE 4 Duration of the compulsory licence

Current law

The current CAMR – *Patent Act* s. 21.09 – states that a compulsory licence issued under the regime "is valid for a period of two years beginning on the day on which the authorization is granted."

Proposed reforms

Bill C-393 would repeal the provision in *Patent Act* s. 21.09 that limits the compulsory licence to a fixed term of two years.

Working group's assessment

The working group agreed that there is no provision in the 2003 WTO Decision or in TRIPS that requires that a compulsory licence be limited to 2 years or to any specific period of time. Therefore, it could not be said that Bill C-393's amendment to remove this current limitation in CAMR was in violation of any provision of WTO law. Rather, TRIPS Article 31 contains two relevant provisions that delimit the duration of a compulsory licence:

- Article 31(c) states, in relation to authorizations without the consent of the patent-holder (i.e., compulsory licences), that "the scope and duration of such use shall be limited to the purpose for which it was authorized."
- Article 31(g) states that "authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances."

Working group's recommendation

To provide further clarity, and to ensure that there is no question that a reformed CAMR complies with TRIPS Article 31, the expert working group recommended that a provision be added to Bill C-393 so as to add to the *Patent Act* (likely in s. 21.14), a provision such as:

> *A patentee may apply to the Federal Court for an order that another person is no longer permitted to export a product that makes use of the patentee's invention to a given country or WTO Member pursuant to an authorization existing or issued under this Act on the basis that either:*
> *a) the country or WTO Member is no longer an eligible importing country or WTO Member; or*

b) *the circumstances which led to the authorization to supply that country or WTO Member have ceased to exist and are unlikely to recur.*

ISSUE 5 Prior negotiations for a voluntary licence

Current law

Under the current CAMR – specifically, *Patent Act* s. 21.04(3)(c) – in no circumstance can a generic manufacturer obtain a compulsory licence without first attempting to negotiate, for a period of at least 30 days, with the patent-holder(s) for a voluntary licence "on reasonable terms and conditions" to export a pharmaceutical product to an eligible importing country.

Proposed reforms

Bill C-393 would remove this provision, and would allow a generic manufacturer to apply directly for a compulsory licence authorizing exports to eligible importing countries, with a condition to pay royalties to the patent-holder(s) pursuant to the existing formula in CAMR.

Working group's assessment

The expert working group agreed that the current CAMR is unnecessarily restrictive, as it goes beyond what is required under TRIPS ("TRIPS-plus") by failing to reflect fully the existing flexibility already found in TRIPS regarding the question of the requirement to seek a voluntary licence before a compulsory licence may issue.

Prior negotiation with the patent-holder(s) is normally required. TRIPS Article 31(b) requires that prior to the issuing of a compulsory licence, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms within a reasonable time period. However, TRIPS Article 31(b) says explicitly that the requirement may be waived by a Member in various situations:

> *(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.*

The expert working group noted that the 30-day period for attempting negotiations set out in the current CAMR (*Patent Act* s. 21.04(3)(c)) is consistent with the TRIPS requirement of making efforts to obtain a voluntary licence from the patent-holder(s) "within a reasonable period of time." The working group also noted that, consistent with TRIPS Article 31(h), Bill C-393 preserves the current requirement under CAMR that, in all cases, a generic manufacturer who obtains a compulsory licence must pay royalties to the patent-holder(s) – and the working

group took note of the provisions in the regulations that determine the royalties payable in relation to any given contract with a given eligible importing country.[4]

However, the working group noted its concern that the current CAMR does not waive the requirement of prior negotiation in those cases explicitly allowed by TRIPS Article 31(b) – namely, emergency circumstances and situations of public non-commercial use – both of which are of significant relevance to such things as ongoing global efforts to scale up access to medicines in developing countries for public health problems, including, but not limited to, such diseases as HIV/AIDS, tuberculosis and malaria.

The working group also discussed that TRIPS Article 30 provides for "limited exceptions" to exclusive patent rights.[5] This could be of potential relevance in determining if and when Canada could waive a requirement of prior negotiation before issuing a compulsory licence – including whether it could simply waive this requirement in all cases, as proposed by Bill C-393. It was agreed that this is an interpretation that could be advanced (as has been done by organizations such as the Canadian HIV/AIDS Legal Network), but it was noted that this interpretation is contested and this is a point on which there is little guidance under TRIPS or the decided cases. As it is therefore not yet possible to say with any certainty whether such an approach is or is not consistent with TRIPS, there was no firm conclusion agreed by the working group on this point.

The working group discussed how best to reflect in CAMR the full flexibility that is clearly available to Canada under TRIPS Article 31(b) and the 2003 WTO Decision while also trying to keep the operation of the Regime straightforward. A difficulty arises because it will not always be entirely clear, at the time of applying for a compulsory licence to supply an eligible importing country or countries, whether all the medicines that could be supplied under that licence will be in response to an emergency situation or are solely for public non-commercial use.

Working group's recommendation

The working group discussed two options that could be reflected in amendments to Bill C-393 and to CAMR.

> ***OPTION 1: Preserve a requirement for prior negotiation in all cases but ensure that it is simple and straightforward for the generic manufacturer to satisfy the 30-day requirement of negotiation and that such negotiation is not contingent on identifying either a specific importing country or a predetermined fixed quantity of product authorized for export under the licence.***

[4] Use of Patented Products for International Humanitarian Purposes Regulations, SOR/2005-143, s. 8.

[5] This provision in TRIPS enables provisions in the law of Canada and other WTO Members such as those that allow generic manufacturers to use a patented pharmaceutical product for purposes of developing a generic version and proceeding through regulatory review processes, in Canada or elsewhere, so as to be able to sell a generic version of a product once the patent expires.

Under this option, Bill C-393 would be amended so as to preserve in *Patent Act* s. 21.04(3)(c) the requirement that the generic manufacture demonstrate to the Commissioner that it has sought a voluntary licence from the patent-holder(s) for a minimum of 30 days. However, this option would only be acceptable if, as proposed in the current bill, Bill C-393 were also to remove from the *Patent Act* the current requirement that the request for a voluntary licence identify a single, specific country and a specific, maximum quantity of medicine to be supplied to that country – as this has already proven, under the current CAMR, to be a significant barrier to satisfying this prior negotiation requirement. Under this option, an amended s. 21.04(3)(c) of the *Patent Act* would read as follows:

> *(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant has, at least 30 days before filing the application, sought from the patentee or, if there is more than one, from each of the patentees, by certified or registered mail, a licence to manufacture and sell the pharmaceutical product for export to one or more of the eligible importing countries named in the Schedule on reasonable terms and conditions, and that such efforts have not been successful.*

This approach has the disadvantage that it does not fully reflect the flexibility already clearly found in TRIPS Article 31(b), because it still requires prior negotiation in all cases, even though this is not required in cases of emergencies or public non-commercial use. However, the advantage of such an approach is its simplicity in applying across the board, and clearly satisfying without any doubt, in every case, the TRIPS requirement of prior negotiation.

> ***OPTION 2: Establish a two-track approach depending on circumstances and affecting the scope of the compulsory licence issued***

An alternative option was discussed by the working group that would have CAMR set out a two-track process for compulsory licensing:

- one process for compulsory licences that would supply pharmaceutical products only for either public non-commercial use or for emergencies or other circumstances of extreme urgency, in which cases the requirement for prior negotiation with the patent-holder(s) would not apply; and
- one process to obtain a compulsory licence that would authorize commercial sector supply of the generic, in which case the generic manufacturer would have to demonstrate unsuccessful efforts at prior negotiation.

The working group agreed that a two-track process for compulsory licensing was legally possible under TRIPS. However, it would be more complex as a matter of legislative drafting, which may make it more difficult to explain in the requisite detail to legislators considering reforms to CAMR already proposed by Bill C-393. It could also potentially result in circumstances where a licence is obtained for a limited purpose (e.g., for public non-

commercial use in an eligible importing country of a generic medicine exported under CAMR) but this then creates an undesirable lack of flexibility in the channels through which developing countries could scale up access to medicines using generics purchased from a Canadian generic manufacturer. The working group offered some general suggestions about how such a two-track compulsory licensing regime might be formulated in the law, but did not have time to craft a specific recommendation with proposed wording. Based on the discussions at the consultation, the Canadian HIV/AIDS Legal Network has prepared some possible wording for consideration by Parliament should this approach be preferred in amending CAMR to take full advantage of the flexibility afforded by TRIPS Article 31(b), which it currently fails to do.

ISSUE 5: Anti-diversion measures

Current law

Currently, CAMR includes a number of measures aimed at preventing the diversion of medicines exported under compulsory licence from being supplied to the intended purchaser(s), including the following:

- Distinguishing features: Under *Patent Act* s. 21.04(3)(b), before the Commissioner of Patents can issue a compulsory licence, the Minister of Health must confirm that the product in question meets the requirements of the Food and Drugs Act and its regulations, including requirements that distinguish the product from the version of the product(s) sold in Canada by the patent-holder(s). The specific requirements set out in the regulations under the *Patent Act* and the *Food and Drugs Act* (Part II) that form part of CAMR and are applicable to any products exported under a compulsory licence issued under CAMR.[6]

- Website postings: Under *Patent Act* s. 21.06, before exporting a product under a compulsory licence, the generic manufacturer must establish a website and post on it the prescribed information, which includes the name of the product being exported, the country to which it is being exported, the quantity authorized for export by the compulsory licence, the distinguishing features of the generic product being exported and of its label and packaging, etc. Under s. 21.14(1)(b), failing to comply with these requirements is grounds for the Federal Court to terminate the compulsory licence.

- Export notices to patentees: Under *Patent Act* s. 21.07, before shipping any quantity of a product authorized under a compulsory licence, the generic manufacturer must provide, within the 15 days before shipment, a notice of the shipment to the patent-holder(s), the recipient country and the person or entity that purchased the product.

[6] Use of Patented Products for International Humanitarian Purposes Regulations, SOR/2005-143; Regulations amending the Food and Drug Regulations (1402 – Drugs for Developing Countries), SOR/2005-141; Regulations amending the Medical Devices Regulations (Developing Countries), SOR/2005-142.

Proposed reforms

Pursuant to Bill C-393's proposed amendments, the *Patent Act* would include the following provisions:

- Section 21.04(3): "The Commissioner shall grant an authorization only if the applicant has complied with the prescribed requirements."
- Section 21.05: "The authorization must be in the prescribed form and contain the prescribed information."
- (new) Section 21.051: "The holder of an authorization shall ensure that all products manufactured under the authorization are labelled in accordance with the prescribed requirements." [It was noted by the working group that this is, in fact, a new provision added to the Patent Act by Bill C-393 that makes it a statutory obligation of the generic manufacturer to comply with any labelling requirements prescribed in regulations.]
- Section 21.06(1): "Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the eligible importing country or countries to which it is to be exported, the quantity of the product being exported to each country and the distinguishing features of the product, and of its label and packaging."

Working group's assessment

The expert working group unanimously agreed that the anti-diversion provisions contained in Bill C-393 comply with WTO requirements, with one exception requiring a minor amendment (see recommendation below). These anti-diversion provisions include

- Distinguishing features: The working group agreed that the existing requirements for differentiating features in CAMR, preserved by Bill C-393, are consistent with paragraph 2(b)(ii) of the 2003 WTO Decision, which requires that products produced under a compulsory licence shall be clearly identified as being produced under the system set out in the Decision through specific labelling *or* marking or through special packaging and/or special colouring/shaping of products. As a result of these sections preserved or added by Bill C-393, the provisions in the regulations which form part of the overall CAMR – and which are made under the *Patent Act* and the *Food and Drugs Act* (Part II) – continue to apply, as does the ability of the Canadian government to prescribe via further regulations should that prove necessary or advisable. These existing regulations about distinguishing features include, for example:

    - the requirement that the generic manufacturer disclose on a website information as to "the distinguishing features of the pharmaceutical product – including its colour if applicable – and of its label and packaging, as required by regulations made under the *Food and Drugs Act*"; [7] and

[7] Use of Patented Products for International Humanitarian Purposes Regulations, SOR/2005-143, s. 7(e).

- the regulations under the *Food and Drugs Act* that apply to generic products produced under a compulsory licence issued under CAMR, which require such measures as permanently embossing a drug in solid dosage form with the mark "XCL" (or the immediate container of a drug that is not in solid form), ensuring that the colour of the drug itself is significantly different from the colour of the version of the drug sold in Canada (in the case of a drug in a solid dosage form), and ensuring that the label of the drug permanently bears the mark "XCL", followed by the export tracking number assigned by Health Canada and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA" (or the French equivalent thereof).[8]

- Website postings: Bill C-393 maintains the current CAMR requirement (*Patent Act*, s. 21.06) that the generic manufacturer post certain information before exporting any product under a compulsory licence, as an anti-diversion measure. This is consistent with the 2003 WTO Decision.

- Export notices: The working group noted one problem with Bill C-393 requiring a minor amendment. Bill C-393 repeals *Patent Act* s. 21.07, which deals with export notices the patent-holder(s), the eligible importing country and the purchaser. (The working group agreed that the current formulation of s. 21.07 is not required by TRIPS or the 2003 WTO Decision.) Bill C-393 also proposes to remove the reference from s. 21.06(1) to the "quantity [of the product] that is authorized to be manufactured and sold for export" under a compulsory licence, as information that the generic manufacturer must post publicly on a website before exporting the product. This change to s. 21.06(1) is proposed because, as discussed above, Bill C-393 would remove the "maximum quantity" limitation on a compulsory licence issued under CAMR – meaning that the current wording of s. 21.06(1) in referring to quantities of the product would no longer make sense if left as is. However, the repeal of both s. 21.07 (export notices) and the deletion of any reference to quantity of the product from s. 21.06 means there would be no clear obligation on the generic manufacturer to disclose the quantity being exported. This is contrary to the 2003 WTO Decision, as paragraph 2(b)(iii) states that: "before shipment begins, the licensee shall post on a website the following information: - the quantities being supplied to each destination…" A minor amendment to s. 21.06 can easily correct this (see recommendation below).

Working group's recommendation

The working group recommended that Bill C-393's wording for a new *Patent Act* s. 21.06(1) should be amended slightly, such that the final text of the new section, as amended, would read as follows:

[8] Regulations amending the Food and Drug Regulations (1402 – Drugs for Developing Countries), SOR/2005-141, s. C.07.008.

21.06(1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the eligible importing country or countries to which it is to be exported, the quantity of the product being exported to each country and the distinguishing features of the product, and of its label and packaging.

Experts participating in the consultation:

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- Peter Maybarduk, J.D., Access to Medicines Program Director, Public Citizen, and Executive Director, International Professional Partnerships for Sierra Leone
- Mike Palmedo, B.A. (Econ.), Assistant Director, Program on Information Justice and Intellectual Property, American University Washington College of Law
- Sisule Musungu, LL.B., Post-graduate Diploma in Law; President of IQSensato, and Chairman of Board of Directors of Health Action International (HAI) Africa
- Emi MacLean, J.D., US Director, Access to Essential Medicines Campaign of Médecins Sans Frontières
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