# Bill C-393:
## Key features and compliance with Canada's WTO obligations

The Canadian HIV/AIDS Legal Network has previously submitted a detailed legal analysis of proposed reforms to Canada's Access to Medicines Regime (CAMR) contained in Bill C-393 (passed by the House of Commons on March 9, 2011).[1] That analysis was also previously submitted to the Senate's Standing Committee on Banking, Grade and Commerce in October 2009 when it studied at length the virtually identical Bill S-232 (which subsequently died on the order paper when Parliament was prorogued in December 2009).[2]

Those submissions outlined how all of the proposed reforms originally contained in Bills C-393 and S-232 – and still contained within Bill C-393 as passed by the House of Commons – are consistent with Canada's obligations as a WTO Member under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), the 2001 WTO Ministerial Council's *Declaration on the TRIPS Agreement and Public Health* ("Doha Declaration"), and the WTO General Council's Decision of August 30, 2003 ("2003 WTO Decision") on the use of compulsory licensing for export to eligible countries. This assessment has been confirmed by an international expert consultation convened by the Legal Network and the UN Development Programme (UNDP) in February 2010.[3]

Before its adoption by the House of Commons, Bill C-393 was amended. As result, Bill C-393 is now much pared down from the full set of amendments originally contemplated in Bill C-393 and the then-identical Bill S-232. Bill C-393 now contains many fewer clauses, consisting only of those amendments to CAMR that are most critical – in particular, the "one-licence solution". However, the substance of those clauses – and their continued compliance with WTO rules – has not been changed.

Nonetheless, it has been incorrectly suggested that Bill C-393's "one-licence solution" does not comply with Canada's WTO obligations; in some cases, those making such claims simply misstate or misinterpret the provisions of TRIPS. Complementing the Legal Network's earlier brief, the chart below outlines in summary form the key issues and the provisions of WTO law that permit Canada to simplify the current CAMR as proposed by Bill C-393, while complying

[1] Canadian HIV/AIDS Legal Network, "Making CAMR Work: Streamlining Canada's Access to Medicines Regime", Brief to the House of Commons Standing Committee on Industry, Science and Technology (October 21, 2010), online via www.aidslaw.ca/camr.
[2] Canadian HIV/AIDS Legal Network, "Making CAMR Work: Streamlining Canada's Access to Medicines Regime", Brief to the Senate Banking, Trade and Commerce Committee regarding Bill S-232 (October 21, 2009), online via www.aidslaw.ca/camr.
[3] "Reforming Canada's Access to Medicines Regime: 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), online via www.aidslaw.ca/camr.

with its legal obligations as a WTO Member — and in some instances, making CAMR even *more* consistent with TRIPS by taking advantage of explicit flexibilities not currently reflected in CAMR.

In reviewing the specific provisions below, it should be recalled that, as a matter of WTO law:

- WTO Members "shall be free to determine the appropriate method of implementing the provisions of this [TRIPS] Agreement within their own legal system and practice": TRIPS Article 1(1).
- WTO Members have agreed that "the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose": *Doha Declaration*, para. 4.
- WTO Members have agreed that the 2003 WTO Decision was adopted "without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the [Doha] Declaration, and to their interpretation": *2003 WTO Decision*, para. 9.

These are important provisions in WTO law already agreed upon, and repeatedly reaffirmed, by all WTO Members, including Canada. They must be kept in mind when considering that Bill C-393 is entirely compliant with the requirements of WTO law.

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| Bill C-393: issuing a compulsory licence before identifying one specific importing country | The ***2003 WTO Decision*** requires that both the *importing* and the *exporting* country file notifications to the TRIPS Council: paras. 2(a) and 2(c). The Decision also requires that the quantity of a product being exported and the importing country(ies) to which it is exported be disclosed by a licence-holder, including by posting on a website, "before shipment begins": para. 2(b)(iii).<br><br>However, nothing in either the 2003 Decision or TRIPS requires that an importing country have been identified before a compulsory licence is issued in the exporting country. Canada is not required to impose this sequence. It is up to the importing country to file its notification with the WTO's TRIPS Council; Canada doesn't need to enforce this via Canadian legislation. However, if Canada wanted to be certain that any exports under a compulsory licence only happen *after* an importing country has filed its notification with the WTO, this can be easily stated as a condition of the compulsory licence (e.g., a condition stating the licence-holder may not export any medicines to a country under that licence until that country has filed such a notification). |
| Bill C-393: ensuring flexibility to address evolving health needs while regulating the quantity of product exported | ***Requirements of the 2003 WTO Decision:***<br><br>▪ Paras. 1(b) and 2(a)(i): importing country must notify WTO of "expected quantities" of product, not "maximum quantities" as currently stated in CAMR.<br><br>▪ Para. 2(b)(i): exporting country must simply ensure that compulsory licence issued includes the condition that *"only the amount necessary to meet the needs of the eligible importing Member(s) many 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."* This condition can be stated in the licence. There is no requirement under WTO rules to impose an absolute, fixed quantity of product that may be exported under a compulsory licence (which is currently a damaging limitation in CAMR).<br><br>▪ A standard condition of any compulsory licence issued under CAMR (which could be set out in regulations as is currently the case), could include the following:<br>o *"This authorization authorizes the named holder to export the named product(s) 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."* |

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| Bill C-393: one licence authorizing exports to <u>more than one country</u> | ***Requirements of the 2003 WTO Decision:***<br><br>▪ Para. 2: repeatedly refers throughout to a "compulsory licence" (in the singular) being issued for purposes of supplying "eligible importing Member(s)" (in the plural).<br>▪ Other jurisdictions allow a single compulsory licence to supply an "importing country or countries" (e.g., European Union: Regulation (EC) No 816/2006). |
| Scope of the compulsory licence | ***Requirements of the 2003 WTO Decision***:<br><br>▪ Para. 2(c): The exporting country must notify WTO of a compulsory licence once issued, the conditions of that licence, and the "the quantity(ies) for which the licence has been granted."<br><br>▪ Under **Bill C-393, *Patent Act*, s. 21.16**, it is already the case that the generic manufacturer is required to disclose, within 15 days, a copy of any agreement to sell the product authorized for export under a compulsory licence, as well as identify the monetary value of that agreement and the total quantity of product to be sold under it. This already serves as notification of the importing countries' needs.<br><br>▪ However, for further clarity, the "quantity(ies) for which the licence has been granted" can easily be stated as a condition in the compulsory licence, and in Canada's notification to the WTO, as follows: *"the amount necessary to meet the needs of eligible importing country(ies) may be manufactured under the licence and the entirety of this production shall be exported to the country(ies) in accordance with the needs which said country(ies) has(have) 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."*<br><br>▪ This would ensure that it is the needs identified by eligible importing countries, who are intended to be able to make effective use of compulsory licensing via CAMR, that determine the quantities produced and exported. |

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| Expanding current Schedule 1 (limited list of eligible products) | Nothing in TRIPS or the 2003 WTO Decision requires a limited list of products that may be produced for export under compulsory licence. In fact, Bill C-393 *more* closely reflects WTO law as agreed by WTO Members by amending the definition of "pharmaceutical product" to reflect exactly the definition that was adopted unanimously by all WTO Members, including Canada.[4]<br><br>***2003 WTO Decision:***<br>1. For the purposes of this Decision:<br>(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included."<br><br>***Doha Declaration*:**<br>1. We recognize the gravity of public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.<br><br>***Definition of "pharmaceutical product" proposed by Bill C-393 (with added text underlined):***<br><br>*"pharmaceutical product" means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product <u>and any other patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, and includes any active ingredients necessary for its manufacture and diagnostic kits needed for its use</u>.* |
| Removing requirement of attempting prior negotiation for voluntary licence: | Contrary to claims by Rx&D and others, which repeat a common misstatement of the law, TRIPS Article 31(b) 7does <u>not</u> contain an across-the-board requirement that attempts at negotiating a voluntary licence with patent-holders(s) must be undertaken before a compulsory licence may issue. Article 31(b) is more nuanced than this.<br><br>In fact, ***TRIPS Article 31(b)*** states explicitly: |

[4] NOTE: Given the wording of the 2003 WTO Decision, it is advisable that CAMR be amended not only to apply to any "drug", as proposed by Bill C-393, but also to any medical "device" as defined in s. 2 of the *Food and Drugs Act*.

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| TRIPS Article 31(b) | "This requirement [of prior negotiation] 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."[5]<br><br>Despite this clear statement in TRIPS, CAMR currently requires efforts at prior negotiation with patent-holder(s) in <u>every</u> circumstance, even when unnecessary — and further imposes the restriction that the start of such negotiations cannot be legally valid until a specific importing country and quantity of medicine are identified: current *Patent Act*, s. 21.04(3). (The "one-licence solution" at the heart of Bill C-393 would remove this unnecessary restriction.) The current CAMR thereby fails to take advantage of clearly-stated flexibility in TRIPS Article 31(b), resulting in an unnecessarily stringent compulsory licensing process.<br><br>Where a compulsory licence is issued to enable the importing country to address circumstances set out in TRIPS Article 31(b) — i.e., emergencies, "other circumstances of extreme urgency" or public non-commercial use — Canada is entirely within its rights under TRIPS to dispense with the requirement of prior negotiation as a precondition to issuing a compulsory licence, and move directly to issuing a compulsory licence upon otherwise-satisfactory application, each application to be considered on its individual merits. This is explicitly stated WTO law, and has been reaffirmed repeatedly by WTO Members, including Canada. |

[5] In addition, TRIPS Article 31(k) states explicitly that: "Members are not obliged to apply the conditions set forth in paragraphs (b) [prior negotiation] and (f) [restriction on compulsory licensing to supplying predominantly the domestic market] where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."

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| Authorization must be considered on individual merits: TRIPS Article 31(a) | Under **Bill C-393*, Patent Act* s. 21.04** would require an individual application to Commissioner of Patents by an individual applicant for an authorization to export a single product, and further requires that the applicant meet any prescribed requirements. Neither TRIPS Article 31(a) nor any other provision of TRIPS or any other WTO instrument imposes additional limitations on consideration of an application for an authorization (e.g., the current CAMR restrictions specifying a single importing country or "maximum quantity" of the product in an application for a licence). |
| Requirement to pay "adequate remuneration" to patent-holder: TRIPS Article 31(h) | Currently, CAMR includes **section 8 of the *Use of Patented Products for International Humanitarian Purposes Regulations*** under the Patent Act, which sets out the formula deemed appropriate by the Governor-in-Council when creating CAMR for calculating the royalty payable by the generic manufacturer in respect of any sales to a given eligible importing country. This formula was proposed by civil society organizations, including the Canadian HIV/AIDS Legal Network, during the drafting process of CAMR and was included as a sensible approach to ensuring certainty for all parties in determining royalties.<br><br>**Bill C-393 makes no changes to this formula**, and *Patent Act* **s. 21.08** maintains the requirement for paying royalties. **Section 21.16** maintains the obligation to disclose a copy of any agreement between a generic manufacturer and a purchaser – which enables calculation of the royalty that is payable to the patent-holder – and prohibits any exportation before this disclosure takes place. **Section 21.14** permits the Federal Court to terminate a licence if this requirement is breached. |
| Independent review of authorization: TRIPS Article 31(i) | TRIPS Article 31(i) requires that the legal validity of a decision to issue a compulsory licence be subject to judicial or other independent review. Canadian administrative law already permits judicial review of a decision by the Commissioner of Patents; nothing in Bill C-393 ousts this application of the generally applicable law. In any event, nothing in Bill C-393 changes the extensive, detailed provisions currently found in CAMR (*Patent Act*, s. 21.17), which allow patent-holders to go to court with a request to terminate a licence or impose a higher royalty rate (higher than the rate already deemed reasonable by the Governor-in-Council in the existing *Regulations*) should they be able to convince the Federal Court of the merit of such a claim. |