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

The Canadian HIV/AIDS Legal Network has submitted a detailed legal analysis of Bill C-393's proposed reforms to Canada's Access to Medicines Regime (CAMR) to the House of Commons Standing Committee on Industry, Science and Technology.[1] That analysis outlines how the proposed reforms 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.

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

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

- 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.

[1] Canadian HIV/AIDS Legal Network, "Making CAMR Work: Streamlining Canada's Access to Medicines Regime" (October 21, 2010), online via www.aidslaw.ca/camr.

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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, including by posting on a website, "before shipment begins": para. 2(b)(iii). 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; ensuring exports under the licence comply with the 2003 WTO Decision can be done with conditions, in the licence and/or the statute, that govern the actions of the licensee.
Bill C-393: ensuring flexibility to address evolving health needs while regulating the quantity of product exported	***2003 WTO Decision:*** ▪ 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. ▪ 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 or by statute. There is no requirement to impose an absolute, fixed quantity of product that may be exported under a compulsory licence. ▪ To offer greater clarity, Bill C-393 could be amended to add the following: o in s. 21.05, add the text of a standard condition of any compulsory licence issued under CAMR that states that the licence authorizes the generic manufacturer *"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"* o in Section 21.06(1): add requirement that, before any shipment, generic manufacturer must post on the web *"the quantity of the product being exported to each country"*

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Bill C-393: one licence authorizing exports to more than one country	***2003 WTO Decision:*** ▪ 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). ▪ Other jurisdictions allow a single compulsory licence to supply an "importing country or countries" (e.g., European Union: Regulation (EC) No 816/2006).
Scope and duration of the compulsory licence	***TRIPS Article 31(c)*** simply says that the scope and duration of a compulsory licence "shall be limited to the purpose for which it was authorized". This does not require that a compulsory licence be limited to a specific quantity of a product or to an arbitrary period of 2 years. The purpose of CAMR is to enable eligible developing countries to use compulsory licensing to obtain more affordable medicines to address public health problems. Public health problems are rarely limited to a period of less than 2 years and the total quantity of a medicine needed will evolve over time as the country addresses a problem. In any event, there would be no reason for a developing country to use CAMR to purchase medicines that are not needed. ***2003 WTO Decision, Para. 2(c)***: The exporting country must notify WTO of a compulsory licence once issued, the conditions of that licence, and the following additional information: ▪ The "quantity(ies) for which the licence has been granted" — this can be stated as a condition in the compulsory licence, and in Canada's notification to the WTO, as: *"the amount necessary to meet the needs of 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(have) notified its(their) needs to the Council for TRIPS."* 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. But as noted above, a clarifying amendment to Bill C-393 could make it even more explicit that the compulsory licence authorizes only the export of quantities notified by the importing countries (to the WTO or to the Government of Canada, as applicable). 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. As suggested above, Bill C-393 could be amended to add (in s. 21.05) the text of a standard condition of any compulsory licence issued under CAMR that states

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	that the licence authorizes the generic manufacturer *"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"*. ▪ The "duration of the licence" — this can be stated as either "indefinite" (i.e., to be coterminous with the remaining patent term) or explicitly stated as "until the expiry of any patent that would otherwise impede the licensee from manufacturing the product for export". ▪ Although it is not required by TRIPS, for greater comfort, Bill C-393 could be amended to add a section to the Patent Act (likely in s. 21.14) stating that a patentee may apply to Federal Court terminating a compulsory licence on the basis that either: o *the country or WTO Member is no longer an eligible importing country or WTO Member; or* o *the circumstances which led to the authorization to supply that country or WTO Member have ceased to exist and are unlikely to recur.*
Repealing 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, by repealing this limited list and instead specifying that CAMR applies to any "drug" as defined under the *Food and Drugs Act*, Bill C-393 *more* closely reflects WTO law as agreed by WTO Members.[2] ***2003 WTO Decision:*** 1. For the purposes of this Decision: (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."

[2] 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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	***Doha Declaration*:** 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.
Removing requirement of attempting prior negotiation for voluntary licence: TRIPS Article 31(b)	Contrary to claims by Rx&D and others, which repeat a common misstatement of the law, TRIPS Article 31(b) does <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. ***<u>(1) Emergencies, other urgent circumstances and public non-commercial use</u>*** In fact, ***TRIPS Article 31(b)*** states explicitly: "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."[3] Despite this clear statement in TRIPS, CAMR currently requires efforts at prior negotiation with patent-holder(s) in every circumstance — 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 current CAMR thereby fails to take advantage of clearly-stated flexibility in TRIPS Article 31(b), resulting in an unnecessarily stringent compulsory licensing process. Where a compulsory licence is issued to enable the importing country to address circumstances set out in Article 31(b) — i.e., urgent circumstances 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.

[3] 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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	(2) Other circumstances In other cases – i.e., in situations other than urgent circumstances or public non-commercial use – the requirement under TRIPS Article 31(b) of prior negotiation remains. However, waiving this requirement for the limited purpose of enabling eligible developing countries to "make effective use of compulsory licensing" to address public health problems — the objective already agreed explicitly by WTO Members in the 2001 Doha Declaration and the very purpose of the 2003 WTO Decision they adopted — may be considered a "limited exception" to exclusive patent rights that is permissible under TRIPS Article 30: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." The full scope of the flexibility afforded by TRIPS Article 30 remains uncertain, as there has been but one substantive decision by the WTO's Dispute Settlement Body (*Canada – Patent Protection of Pharmaceutical Products*, Panel Report, WT DS114/R, 2000). The legal assessment of a "limited exception" such as the one proposed by Bill C-393 — i.e., waiving the requirement of prior negotiation in non-urgent, non-public-use circumstances when seeking a compulsory licence for the limited purpose of fulfilling WTO Members' stated objective in the 2003 WTO General Council Decision — is rather different than the situation addressed in that single case. ***In any event, contrary to claims by Rx&D, this is the only aspect of Bill C-393's proposed reforms which requires reference to any provision of WTO law other than the 2003 Decision or TRIPS Article 31. All other reforms proposed by Bill C-393 are fully consistent with both Article 31 and the 2003 Decision. This reform requires the use of other flexibilities in TRIPS, which were explicitly preserved in law by WTO Members in the 2003 WTO Decision.***

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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., specifying a single importing country or "maximum quantity" of the product).
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. 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. Nothing in TRIPS or in the 2003 WTO Decision requires the extensive, detailed provisions currently found in CAMR (*Patent Act*, s. 21.17), which are aimed not at a review of the validity of the decision to issue a compulsory licence but instead at enabling patent-holders to litigate in an effort to terminate a licence or impose a higher royalty rate (than the rate already deemed reasonable by the Governor-in-Council in the existing *Regulations*).