



Canadian
HIV/AIDS
Legal
Network | Réseau
juridique
canadien
VIH/sida

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
Ottawa

Richard Elliott
Executive Director
Canadian HIV/AIDS Legal Network
600-1240 Bay Street
Toronto, Ontario M5R 2A7
+1 416 595-1666 ext. 229
www.aidslaw.ca

Contents

Summary of key reforms to CAMR

1. About the Canadian HIV/AIDS Legal Network
2. Background to Canada's Access to Medicines Regime
3. Streamlining CAMR: the "one-licence solution"
 - 3.1. Current licensing process under CAMR is cumbersome and user-unfriendly
 - 3.2. The simple, efficient alternative: Bill S-232's "one-licence solution"
4. One-licence solution is consistent with Canada's WTO obligations
 - 4.1. Issuing a compulsory licence before a specific importing country is identified
 - 4.2. Ensuring flexibility while regulating the quantity of product exported
 - 4.3. Issuing one licence authorizing exports to more than one country
 - 4.4. Removing the prerequisite of attempting to negotiate a voluntary licence
5. Addressing other common misinformation and objections to proposed CAMR reforms
 - 5.1. Bill S-232 preserves anti-diversion safeguards
 - 5.2. Bill S-232 preserves and enhances options for reviewing quality of exported medicines
6. Conclusion

Appendix: Bill S-232 amendments to the *Patent Act* and the *Foods and Drugs Act*

"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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."

"We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."

— WTO Ministerial Council, "Declaration on the TRIPS Agreement and Public Health" (2001)

Summary of key reforms to CAMR

Canada's Access to Medicines Regime (CAMR) is not delivering on Parliament's pledge to help developing countries get affordable medicines. The Canadian HIV/AIDS Legal Network endorses the amendments proposed in Bill S-232 that will help fix the current, flawed Regime as follows:

- **Bill S-232 enacts a “one-licence solution” to streamline the current compulsory licensing process that is unnecessarily cumbersome, repetitive, inflexible and inefficient.** Currently, CAMR limits a compulsory licence to fulfilling only a single order by a single country for a pre-determined “maximum quantity” of a medicine, and this only after a cumbersome process of attempted negotiation with patent-holders and a subsequent application to the Commissioner of Patents — which process must then be repeated anew for every single drug order for each individual country. Instead, under Bill S-232, a generic manufacturer first makes an application to the Commissioner of Patents for an authorization to export a given pharmaceutical product. Once the Commissioner has confirmed that the application complies with the legislative requirements, the authorization issued permits the manufacturer to export that product to any of the eligible countries already specified in the legislation. Under this “one-licence solution”, the authorization is not limited to exporting a fixed quantity of a medicine and to only a single country; therefore, it would not require a new application process for every single (tentative) agreement negotiated between a generic manufacturer and a single importing country. Such an approach provides more certainty and clarity for all parties involved in such transactions, and eliminates much of the red tape that dissuades use of the current regime. In addition, by allowing generic suppliers to work with multiple eligible countries at a time, a one-licence approach also facilitates economies of scale that make prices of medicines for those countries even more competitive.
- **Bill S-232 eliminates the arbitrary and counter-productive limit of 2 years on the duration of an authorization** to export a generic medicine to eligible developing countries. This provides for flexibility and sustainability in responding to countries' evolving needs. It also further facilitates economies of scale that would make CAMR more effective by lowering prices further and thereby helping more people get medicines with limited resources.
- **Bill S-232 eliminates the current limited list of products that can be made in generic form for export**, and instead adopts a broader, yet clear, definition that is *more* reflective of WTO law than the current legislation.
- **Bill S-232 preserves the option of Health Canada review** and approval of a generic product before it is exported, but **also provides for equally acceptable alternatives** such as review by another equally stringent drug regulatory authority acceptable to the importing country or by the World Health Organization's Prequalification Programme set up for this purpose.
- **Bill S-232 makes it easier for humanitarian organizations operating in developing countries to purchase Canadian-made generic medicines for treating patients** in eligible countries, by eliminating the additional CAMR requirement (found nowhere in WTO law) that they obtain the “permission” of the importing country government.
- **Bill S-232 treats non-WTO developing countries fairly:** it eliminates the discriminatory additional requirements currently imposed by CAMR on such countries that wish to benefit their people by importing Canadian-made generics — restrictions that do not apply to developing countries belonging to the WTO and that are not required under any WTO law.

1. About the Canadian HIV/AIDS Legal Network

The Canadian HIV/AIDS Legal Network (www.aidslaw.ca) promotes the human rights of people living with and vulnerable to HIV/AIDS, in Canada and internationally, through research, legal and policy analysis, education and community mobilization. The Legal Network is a non-governmental organization (NGO) in Special Consultative status with the Economic and Social Council of the United Nations. The Legal Network has provided technical advice and analyses on various HIV-related legal issues, including matters of international law and access to medicines, to the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Office of the UN High Commissioner on Human Rights (OHCHR), the UN Development Programme (UNDP) and the World Health Organization (WHO).

The Legal Network was actively involved in discussions leading up to the passage in 2004 of the legislation that established “Canada’s Access to Medicines Regime.” Among other things, the Legal Network provided extensive input to federal government ministers and officials during the drafting of the legislation, appeared before the House of Commons Standing Committee on Industry, Science and Technology in February 2004, and provided a series of detailed submissions to the Committee regarding various aspects of the then-draft legislation. A number of our proposals were reflected in amendments adopted by the Committee. We have actively supported efforts to make use of CAMR since it was created in 2004 as a mechanism to help scale up access to AIDS treatment and other medicines in the developing world.

However, the Legal Network, along with a wide range of other Canadian civil society organizations and various international experts (on medicines procurement, international trade and intellectual property law, and human rights), has also been critical of the deficiencies in CAMR since it was created. We again raised numerous concerns, and proposed reforms to address those concerns, in April 2007 before the House of Commons Standing Committee on Industry, Science and Technology.¹ The same month, we co-hosted an international expert consultation in Ottawa with more than 60 participants from around the world, including: representatives from UN agencies and the Global Fund to Fight AIDS, Tuberculosis and Malaria; Canadian government officials; representatives of government agencies and NGOs from developing countries in Africa, Asia and Latin America who are responsible for pharmaceutical procurement and distribution; leading medical professionals involved in scaling up access to AIDS treatment in developing countries; human rights advocates; and several leading international legal experts (including from the WTO) intimately familiar with the WTO’s *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) and the negotiations over the last decade regarding patents WTO patent rules and access to medicines.² Those discussions have helped inform our assessment of CAMR and its operational deficiencies, as well remedies for those deficiencies that make the Regime workable while complying with Canada’s obligations under TRIPS.

¹ Canadian HIV/AIDS Legal Network, “Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export – Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Canada’s Access to Medicines Regime”, 18 April 2007, online: <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=705>. That brief provides a detailed analysis of various deficiencies in CAMR and recommended reforms.

² See Canadian HIV/AIDS Legal Network & North-South Institute, “Meeting Report: Access to Medicines and Intellectual Property: An International Expert Meeting on Canada’s Access to Medicines Regime, Global Developments, and New Strategies for Improving Access”, Ottawa, 19-21 April 2007, online: <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=792>.

2. Background to Canada's Access to Medicines Regime

Under the WTO's *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS"), WTO members are free to issue *compulsory licences* that authorize someone other than the patent-holder to make, use and sell a generic version of a patented pharmaceutical product. This freedom was reaffirmed explicitly in 2001 by all WTO Members in their unanimous *Declaration on the TRIPS Agreement and Public Health* ("Doha Declaration").³ However, TRIPS Article 31(f) restricts the use of compulsory licensing to authorize the production of generics for export, stating that any such use of a patented invention could only be authorized "predominantly for the supply of the domestic market of the Member authorizing such use". In the 2001 Doha Declaration (paragraph 6), WTO Members recognized that countries with insufficient pharmaceutical manufacturing capacity face difficulties in "making effective use of compulsory licensing under the TRIPS Agreement" because of this restriction. On August 30, 2003, WTO Members unanimously adopted a General Council Decision that temporarily waived this restriction ("WTO Decision").⁴

Based on this Decision, in May 2004, Parliament unanimously enacted *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, S.C. 2004, c. 23, thereby establishing what is now referred to as "Canada's Access to Medicines Regime" ("CAMR" or "the Regime"). This legislative scheme is intended to enable compulsory licensing of patented pharmaceuticals for the purpose of exporting less-expensive generic products to eligible developing countries to address public health problems. Such measures are needed to assist countries that cannot pay the higher prices charged by patent-holders for brand-name, originator drugs but need to import generic medicines because they lack sufficient domestic capacity to manufacture them to meet their needs. Canada's legislation came into force in May 2005; the accompanying regulations came into effect in June 2005. However, despite concerted efforts, the Regime has delivered next to nothing.

As recognized by the Government of Canada in its November 2006 consultation paper during the mandatory review of CAMR: "Despite being in force since May of 2005, CAMR has not yet resulted in the export of any eligible pharmaceutical products to eligible importing countries. Similarly, there have been no exports under comparable regimes in other countries that have implemented the WTO waiver."⁵ **The Senate Standing Committee on Foreign Affairs and International Trade recommended in 2007 that Canada should "amend Canada's Access**

³ *Declaration on TRIPS and Public Health*, WTO Doc. WT/MIN(01)/DEC/2, 14 November 2001 ("Doha Declaration").

⁴ WTO General Council, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health", Decision of the General Council of 30 August 2003, WTO Doc. WT/L/540 and Corr.1, online: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm ("2003 WTO Decision"). Subsequently, in December 2005, WTO Members agreed to convert this temporary waiver into a permanent amendment to the TRIPS Agreement, to take effect once two-thirds of WTO Members had formally accepted it. That target has not yet been reached and the deadline for reaching it has been extended until December 2009. Canada notified its acceptance of the waiver as a permanent amendment on 16 June 2009. For more information, see: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm. Health advocates have been critical of the rush to make permanent a waiver that has shown itself to be largely unworkable.

⁵ Government of Canada, "Canada's Access to Medicines Regime – Consultation Paper", 11 November 2006, p. 2 (Section 3.0), online: http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult-eng.php.

to Medicines Regime, including its underlying legislation, to make it more effective in prompting shipments of medications for HIV/AIDS sufferers to Africa.”⁶ In December 2007, the Government’s report of its review of CAMR noted that, by that point, there had been only one shipment of one generic AIDS drug to one country (Rwanda), but nonetheless concluded that it was premature to make any amendments.⁷ All the Government was willing to, offer was that it would “continue to closely monitor developments, both domestically and in other countries that have implemented the WTO waiver, in the hopes that further eligible importing countries will come forward to request pharmaceutical products.”⁸ More recently, the Government has stated that its report “does not close the door to future amendments and affirms the government’s continued commitment to support the use of CAMR as a vehicle for facilitating access to low-cost medicines in developing countries.”⁹

Since those assessments in 2007, there has been no other compulsory licence issued and no other generic manufacturer or developing country has indicated willingness to use CAMR as it stands — although the one manufacturer that has obtained the one licence under CAMR has publicly committed to attempting to supply a paediatric combination AIDS drug suitable for children with HIV to developing countries if the process can be made workable. It remains the case that only one country has benefited from one order of one medicine. There is no doubt of the tremendous need in the developing world for affordable, simple medicines for AIDS and numerous other diseases. Yet so far, CAMR has done little to address the need and is unlikely to do anything further absent reforms. The toll of preventable deaths and terrible suffering has risen while Canada’s much-vaunted pledge to help has gone unfulfilled. More than six years since it was created, CAMR cannot be considered a success by any honest measure.

The possible use of a compulsory licensing regime such as CAMR is influenced by a variety of larger political and economic factors. Canada cannot, through legislation, address all of the factors that may dissuade developing countries from taking advantage of options such as compulsory licensing to obtain less expensive medicines. However, the Government and Parliament can craft Canada’s legislative regime to take account of the practical considerations that face both generic manufacturers and developing countries as the producers and procurers, respectively, of medicines that could be supplied under compulsory licences. The reforms proposed in Bill S-232 reflect such an approach. By making CAMR much simpler and user-friendly, Bill S-232 dramatically increases the prospects that it will be used again in the future.

⁶ Senate Standing Committee on Foreign Affairs and International Trade, “Overcoming 40 Years of Failure: A New Road Map for Sub-Saharan Africa”, February 2007, p. 117, online: <http://www.parl.gc.ca/39/1/parlbus/commbus/senate/com-e/fore-e/rep-e/repafriFeb07-e.pdf>. It should be recalled that CAMR’s scope extends beyond just AIDS medicines for African countries.

⁷ “While there may be room to improve CAMR, as there is with any legal framework, more time, evidence and analysis is needed to determine if changes to these features, along the lines of the amendments proposed by various stakeholder groups, would make a meaningful difference in the volume and frequency of exports.: Government of Canada, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act*, 14 December 2007, online: http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport_e.html.

⁸ Ibid., p. 40.

⁹ Hon. Jim Prentice (Minister of Industry), Letter dated 28 April 2008 to Canadian Council for International Co-operation, Canadian HIV/AIDS Legal Network and Oxfam Canada [on file].

3. Streamlining CAMR: the “one-licence solution”

CAMR has not delivered on Parliament’s promise, in part because it is marred by numerous unnecessary features that make it cumbersome and complicated for would-be purchasers seeking to import medicines into developing countries and for would-be generic producers in Canada — to the point that it effectively deters those who might otherwise be interested in using the Regime. Therefore, the Government and all parliamentarians would miss the mark by simply tinkering at the margins with a few minor amendments to CAMR.

The central objective must be to fix the Regime’s current unwieldy process for authorizing the exportation of generic pharmaceuticals to eligible countries. The most significant reform, as proposed by Bill S-232, would replace the existing process for obtaining a compulsory licence with a simple “one-licence” approach that is much more streamlined and user-friendly — and hence more likely to be effective — while respecting Canada’s obligations as a member of the World Trade Organization.

In this section, we set out why this core reform is needed, outline how a “one-licence” process would function, and address the incorrect claim that such an approach contravenes Canada’s WTO obligations. In the next section, we address some other common but misguided objections to the bill. (As noted above, more detailed analysis of other reforms now proposed in Bill S-232 to other aspects of CAMR can be found elsewhere.¹⁰)

3.1 Current licensing process under CAMR is cumbersome and user-unfriendly

In its current form, CAMR is cumbersome and difficult to use. As the commentary below illustrates, there are too many hurdles that developing countries must clear before they can place an order and receive the medicines. The legislation is layered with restrictions and regulatory requirements which go beyond what is required by WTO law. As it stands now, the law contains over 100 clauses. Simply understanding the law requires legal training; in both developing and developed countries it is doctors or other health professionals, not lawyers, who place orders for drugs. Consider, by way of contrast, that some other WTO Members have adopted shorter, simpler legislation to permit compulsory licensing of pharmaceuticals for export. While some of those regimes suffer from their own deficiencies, including in some cases an unfortunate lack of specificity or clarity that partially explains why they have not been used, they illustrate that it is possible to implement the 2003 WTO Decision more simply.¹¹

¹⁰ See: Canadian HIV/AIDS Legal Network, “Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export – Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Canada’s Access to Medicines Regime”, 18 April 2007, online: <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=705>.

¹¹ For example, when India made amendments in 2005 to bring its domestic patent law into compliance with the TRIPS Agreement, it included a single section, with 3 short subsections, to implement the 2003 WTO Decision in a manner that is fully TRIPS-compliant (albeit one that suffers various operational difficulties that can and should be addressed). *Patents Act, 1970*, (new) Section 92A: (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him. (3) The provisions of

Canada is the first country to have enacted detailed legislation to implement the WTO decision — and the only country to export one order of a desperately needed medicine, thanks to years of work by one company and various NGOs, plus the intervention of a international organization as broker. Such time and effort is obviously not sustainable for every use of the Regime, nor should it be necessary. Consequently, Canada is well-positioned to show leadership by acknowledging that the current approach, while an important initiative, does not offer the rapid, flexible, sustainable solution that is needed.

WTO Members declared that their 2003 Decision represented the “expeditious solution” to the problems faced by countries with insufficient pharmaceutical manufacturing capacity in “making effective use of compulsory licensing” to obtain less expensive pharmaceuticals to address public health problems, as promised in the 2001 Doha Declaration. Yet despite efforts that began in May 2004, shortly after CAMR was created by Parliament as Canada’s implementation of the 2003 WTO Decision, experience over more than 5 years has illustrated that the Decision, as implemented in Canada and elsewhere, is “neither expeditious, nor a solution”.¹²

This experience suggests that there is a fundamental problem with the licensing mechanism embodied in Canada’s law, which ignores the realities of both generic drug manufacturers and developing countries. The current CAMR legislation limits an authorization to fulfilling only a single order for a pre-determined quantity of a medicine by a single country (identified in advance as a precondition of applying for a licence), and even this only after a cumbersome process of attempted negotiation with patent-holders and application — which process must then be repeated anew for every single drug order for each individual importing country.

Yet developing countries need simple contractual processes that will ensure sustainable supplies of essential medicines or other pharmaceutical products; these contracts must be flexible enough to adjust to changing needs. CAMR, forces generic manufacturers through unnecessary hurdles to get a licence to manufacture and export each patented drug, and even then the licence allows for export to a single country in a pre-negotiated quantity for at most two years. Canada needs to streamline the legal process so that developing countries and generic manufacturers can easily use CAMR.

3.2 The simple, efficient alternative: Bill S-232’s “one-licence solution”

Rather than the current process under CAMR, Bill S-232 proposes to put in place a much simpler process of compulsory licensing that is straightforward for all parties and much more efficient — all of which is ultimately to the benefit of patients in developing countries needing sustainable access to more affordable medicines.

sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

Explanation.—For the purposes of this section, “pharmaceutical products” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

¹² Médecins Sans Frontières, *Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable – An Illustration Through Canada’s Jean Chrétien Pledge to Africa*, August 2006, online: http://www.msf.ch/fileadmin/user_upload/uploads/communiqués/images_2006/pdf/came_Neither_expeditious_nor_a_solution_-_August_30_and_the_JCPA_single_page.pdf.

The “**one-licence solution**” proposed by Bill S-232 works as follows:

1. A generic manufacturer first makes an **application to the Commissioner of Patents for an authorization to export a specific pharmaceutical product**. Consistent with the 2003 WTO Decision’s definition, an application could be sought for authorization to export any “pharmaceutical product”, rather than just a product that is on the limited list currently found in CAMR.¹³ (In the case of exporting a “combination” generic product, the product to be exported would combine several different medicines into a single product so as to simplify not only storage and distribution, but also treatment regimens — this is particularly important, for example, for treatment for HIV and malaria where effective treatment requires the administration of multiple medicines.¹⁴ Consequently, the generic manufacturer’s application would identify the relevant patents held by different patent-holders for different medicines that are incorporated into the combination generic product.)
2. The Commissioner makes a decision about each application for a compulsory licence “on its individual merits”, as required by TRIPS Article 31(a). Once the Commissioner has confirmed that the application complies with the legislative requirements, the **Commissioner issues the authorization to the manufacturer**. As is currently the case under CAMR, and consistent with TRIPS, that **licence is “non-transferable”**: it can only be used by the generic manufacturer that applied for it and cannot be assigned to another. The **licence is also “non-exclusive”**: it does not prevent the company holding the patent on the pharmaceutical from continuing to market its product in any country, nor does it prevent another generic manufacturer from also applying for its own licence.
3. The authorization issued by the Commissioner **permits the generic manufacturer to export the product to any eligible importing country or countries already specified in the Schedule** to the *Patent Act* as being eligible importers (consistent with the 2003 WTO Decision), rather than the current CAMR approach of limiting a licence to supplying just one country named in the application to the Commissioner. In addition, the authorization contains **no arbitrary limit of a predetermined “maximum quantity” of that medicine supplied to a single country** (as is currently the case under CAMR), and **contains no arbitrary limit of only 2 years’ duration**. Granting a broader authorization, without these limiting features,

¹³ Paragraph 1(a) of the 2003 WTO Decision states explicitly that:

“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;

We suggest that Bill S-232 could be improved even further, and more fully reflect the 2003 WTO Decision, by adding explicitly in the definitions section (s. 21.02 of the *Patent Act*) that “pharmaceutical product” also includes any “device” as defined in section 2 of the *Food and Drugs Act*.

¹⁴ The generic AIDS medicine exported to Rwanda once under the single licence issued under CAMR was a “triple fixed-dose combination” (FDC) of the three antiretroviral drugs zidovudine (AZT), lamivudine (3TC) and nevirapine (NVP), meaning that under the current law, negotiations were required with multiple patent-holders before an application could be filed with the Commissioner of Patents for a compulsory licence covering the different patents otherwise preventing production of the generic FDC for export.

makes it simpler to supply multiple eligible countries on an ongoing, flexible basis to address evolving needs over time.

4. The authorization issued by the Commissioner contains, as a standard condition, that the **generic manufacturer receiving the licence must pay royalties** to the company (or companies) holding the relevant patent(s) in Canada on the original product(s) as defined in or under the legislation (e.g., in regulations). This complies with the requirement under TRIPS Article 31(h) (and referenced in paragraph 3 of the 2003 WTO Decision) that the patent-holder be paid “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization” to the importing country. Bill S-232 maintains the requirement that the generic manufacturer disclose basic details about not only the quantity of the product being exported to one or more countries, but also the monetary value of the agreements it negotiates to supply developing countries under the authorization it obtained at the outset from the Commissioner, for purposes of determining the royalties that must be paid. CAMR already contains, in regulations made under the *Patent Act*, a sensible formula that calculates the royalty payable on any given contract based on the UN Human Development Index ranking of the importing country.¹⁵ Bill S-232 preserves this positive feature.
5. Should the generic manufacturer fail to comply with its obligations under the Act or a condition of the licence issued by the Commissioner of Patents, the **authorization may be terminated for non-compliance**.

The “one-licence” approach set out in Bill S-232 is **more certain, economical and flexible** for importing developing countries and generic suppliers, eliminating much of the red tape that is a disincentive to use of the current regime:

- **Greater certainty:** With the authorization already obtained at the outset of the process, a generic manufacturer knows with certainty that, if it produces a generic version of the medicine in question, it will be able to manufacture that product should it succeed in bidding to supply developing countries a quality product at a competitive price. (Under CAMR as it stands, a generic manufacturer can only seek the necessary compulsory licence after an importing country and a “maximum quantity” of the product have been specified.)
- **Flexibility:** Because the authorization is already in hand, and is not limited to supplying a specific importing country with a pre-determined “maximum quantity” of a medicine, the generic manufacturer is able to negotiate multiple supply agreements with multiple developing countries on an ongoing, flexible basis — not just one-off agreements on a country-by-country, order-by-order basis for which a separate licence must then be obtained each time, as is currently the case under CAMR. Developing countries are not faced with the unrealistic task of guessing the quantity of the drug that will be needed in a given time period, which quantity will then be the maximum quantity allowable under the compulsory licence issued under CAMR to the generic supplier. Instead, adjustments in the quantity produced and purchased could be made to meet fluctuating needs without having to undertake the entire cumbersome application process anew.¹⁶

¹⁵ “Use of Patented Products for International Humanitarian Purposes”, SOR/2005-143, s. 8.

¹⁶ Note that after the one compulsory licence was issued under CAMR in 2007, the importing country (Rwanda) determined that it would require additional quantities of the product in question (Apo-Triavir, consisting of AZT+3TC+NVP), beyond what the compulsory licence authorized the generic manufacturer

- **Economies of scale:** There are considerable economies of scale that could be achieved with requiring only a single licence to supply a medicine to multiple countries over time are considerable — e.g., the ability of the generic manufacturer to negotiate even lower prices from its suppliers when purchasing active pharmaceutical ingredients in bulk; spreading fixed costs of the manufacturing process over a large production run; avoiding transaction costs of multiple licensing negotiations and applications; etc. This contributes to the goal of encouraging generic manufacturers to participate in using the Regime, and obviously, to lowering further the ultimate price developing countries could negotiate with the generic manufacturer, making limited resources benefit even more people in need of medicines.¹⁷

Finally, the one-licence solution in Bill S-232 also takes account of the practical global reality that, despite repeated assertions at the WTO that all Members have the right to use TRIPS flexibilities such as compulsory licensing to address public health needs, developing countries have faced years of well-documented pressure to refrain from availing themselves of this option even in the face of terrible and growing need. This has included not only litigation and other threats by patent-holding pharmaceutical companies, but also efforts by powerful WTO Members in negotiations over the 2003 WTO Decision to impose unethical and unsound limitations on the scope of diseases for which generic medicines can be obtained through compulsory licences, as well as threats of trade sanctions by some countries (e.g. by the United States against South Africa).¹⁸ By making the authorization to the generic manufacturer in

to provide. If the generic manufacturer is to continue supplying the product, a new compulsory licence will need to be obtained.

¹⁷ In its 2007 report of its review of CAMR, the Government acknowledged that: “In particular, it appears that CAMR could be more explicit in allowing for the harnessing of economies of scale through the pooling of purchasing power by multiple developing countries suffering from the same public health problem. This approach finds support in the August 2003 Decision, which encourages the re-exportation of products imported under the waiver between similarly afflicted countries that are part of the same regional trade group”: Government of Canada, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act*, 14 December 2007, p. 37, online: http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport-eng.pdf. Very recently, the WTO Director General has stated: “Indeed, the system explicitly recognizes the need to create economies of scale for procurement initiatives in regions with a significant proportion of least-developed countries (LDCs). The system is open more generally to the coordination of import needs and source countries so as to ensure the necessary economies of scale”: WTO Director-General Pascal Lamy, “Strengthening Multilateral Cooperation on IP and Public Health”, Address to WIPO Conference on Intellectual Property and Public Policy Issues, 14 July 2009, online: http://www.wto.org/english/news_e/sppl_e/sppl131_e.htm.

¹⁸ Such threats have been made notwithstanding the historical and current use of compulsory licensing or other measures overriding exclusive patent rights, including on pharmaceuticals, by high-income countries (e.g., the U.S. and Canada in 2001 in an effort to purchase stockpiles of less expensive ciprofloxacin for use in the event of bioterrorist attacks with anthrax): see, e.g., J. Reichman & C. Hazensahl, *Non-Voluntary Licensing of Patented Inventions: The Canadian Experience* (UNCTAD/ICSTD, October 2002), online: www.iprsonline.org/unctadictsd/docs/reichman_hasenzahl_Canada.pdf. They have also been made despite the fact that such conduct runs counter to the letter and spirit not only of agreements reached at the WTO (such as the 2003 WTO Decision) but also those states’ obligations under international human rights law. (For example, Canada has a legal obligation under the international human rights treaties it has ratified to take steps, individually and through international assistance and cooperation, to prevent, treat and control epidemic and other diseases: *International Covenant on Economic, Social and Cultural Rights*, 993 U.N.T.S. 3, Articles 2 & 12(c).) This kind of pressure is one factor, among others, that has

Canada the first step in the process, rather than the last, and by not making this authorization contingent on one single country having already been identified in advance (as well as its pre-determined quantity of medicine), there would be no need for a developing country interested in possibly purchasing a generic medicine from a Canadian manufacturer to first step forward and risk retaliation from patent-holders or other governments (such as those that have repeatedly demonstrated their opposition to developing countries using compulsory licensing) — all for the uncertain reward of purchasing one medicine in a predetermined quantity for a limited period of time (assuming the generic manufacturer then ultimately succeeds in obtaining the requisite licence under the current Regime's rules). A one-licence process that begins with the generic manufacturer in the exporting country first obtaining the authorization needed to supply, and then supplying multiple countries at a time on an ongoing, flexible basis, goes some way toward making the prospect of using a compulsory licensing system to import generic medicines more appealing to developing countries facing competing pressures to refrain from such a course.

In summary, such a streamlined, straightforward process as proposed by Bill S-232 would give generic manufacturers and developing countries much more incentive to make use of the Regime to get medicines to patients in developing countries that need them. Already noted above are some of the ways in which the one-licence solution proposed by Bill S-232 is consistent with TRIPS (and indeed, in some ways is more consistent with the letter and the spirit of the 2003 WTO Decision than the current Regime, such as encompassing all pharmaceutical products). The next section discusses in more detail how the “one-licence” approach is in compliance with Canada's obligations under TRIPS.

almost certainly contributed to the lack of use of the WTO Decision and CAMR that ostensibly enable the use of compulsory licensing to obtain more affordable, generic medicines.

4. “One-licence solution” is consistent with Canada’s WTO obligations

Contrary to the incorrect claims from some quarters, the simpler, more straightforward “one-licence” approach set out in Bill S-232 is consistent with Canada’s obligations as a WTO Member. There are three key, related instruments in WTO law to which regard must be had in this assessment: (1) the TRIPS Agreement; (2) the 2001 Doha Declaration; and (3) the 2003 WTO Decision on compulsory licensing for export (and the accompanying Chairperson’s Statement made at the time of its adoption by the WTO’s General Council). The key significance of the Doha Declaration, which does not contain detailed provisions such as those found in TRIPS or the 2003 Decision, is that WTO Members unanimously 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,” and that WTO Members have the right “to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.” This directive applies across the board in assessing the compliance of CAMR and reforms such as those proposed in Bill S-232. With reference to these instruments in WTO law, the reforms proposed in Bill S-232 are consistent with Canada’s WTO obligations for the reasons that follow.

4.1 Issuing a compulsory licence before a specific importing country is identified

“In testimony before [the House of Commons Standing Committee on Industry, Science and Technology], representatives of the [generic] company indicated they had been prepared to seek an export licence as early as July of 2006, but were unable to proceed to the application stage of this process because of the requirement that they identify an eligible importing country in the voluntary licence request to the patent holder.”

— Government of Canada, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act* (2007)

Currently, CAMR requires that the process of trying to get a licence to export from Canada can only get underway once a specific importing country is named — first to the patentee in the 30-day effort to seek a voluntary licence and then, if unsuccessful, in the application for a compulsory licence submitted to the Commissioner of Patents. Bill S-232’s “one-licence solution” would abolish this requirement that makes obtaining a licence contingent upon first identifying the importing country (as well as the “maximum quantity” of the product to be exported to that country). This would not in any way violate Canada’s WTO obligations.

The TRIPS Agreement says nothing about the sequencing of the compulsory licensing process. **More importantly, nowhere does the 2003 WTO Decision state that a compulsory licence may only be issued in the exporting country after a specific importing country, and the quantity of medicines it needs, have been identified.**

The 2003 WTO Decision *does* impose requirements on both the importing country and the exporting country to file certain notifications with the WTO’s Council for TRIPS; in addition, an

exporting country must require that a generic manufacturer exporting under a compulsory licence post certain information publicly on a website:

- Notification by importing country: Under paragraph 1(b) (defining “eligible importing Member”) and paragraph 2(a) (regarding notification to the Council for TRIPS by the importing Member), the importing country must notify the WTO of its “expected quantities” of the product. (NB: This differs from the “maximum quantity” that CAMR currently requires be stated in the generic manufacturer’s request for a voluntary or compulsory licence. In this respect, CAMR is unnecessarily more restrictive than the WTO Decision.)
- Website posting by generic manufacturer: Under paragraph 2(b)(iii), the compulsory licence issued by the exporting country must include a condition requiring that the generic manufacturer post on a website the quantities of the product being supplied to various destinations “before shipment begins.”
- Notification by exporting country: Under paragraph 2(c), the exporting Member must notify the WTO of any compulsory licence it issues on a patented pharmaceutical product (or products) to permit export, and of the conditions attached to such a licence. This notification must include “the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence.” In addition, this notification by the exporting country must indicate the address of the website that the generic manufacturer must establish as a condition of the licence (noted above).

These provisions appear in the WTO Decision for purposes of ensuring transparency and monitoring the use of the system — which importing countries and generic suppliers, for which medicines and in what quantities. However, the WTO Decision does not state that either the notification from the importing country, or the notification from the exporting country that a compulsory licence has been issued, must happen before a compulsory licence is issued to the generic manufacturer.

It *is* the case, as noted above, that the importing country’s notification to the TRIPS Council must happen before the generic manufacturer actually ships any product produced under the compulsory licence: paragraph 2(b)(ii) of the WTO Decision says that the generic manufacturer must post on its website, “before shipment begins”, the quantities being supplied to each destination country “as referred to” in paragraph 2(b)(i), which clause states that the entirety of the product manufactured under the compulsory licence “shall be exported to the Member(s) which has notified its needs to the Council for TRIPS”. These clauses indicate that the generic manufacturer may not ship its product until the importing country (or countries) has/have indicated the quantity of product needed by way of notification to the WTO, but nothing prevents the compulsory licence from being issued in advance of an importing country filing its notification.

Conclusion: There is nothing in the 2003 WTO Decision (or in TRIPS) that says that an importing country must be identified before a compulsory licence can be issued to a generic manufacturer in the exporting country. So, it is not necessary that CAMR impose this sequencing requirement of identifying the importing country before a licence can be issued. Bill S-232’s simpler procedure of issuing

one licence that is not contingent upon advance disclosure of a single importing country in no way contravenes Canada's WTO obligations.

4.2 Ensuring flexibility while regulating the quantity of product exported

Currently, CAMR limits the benefit and flexibility of a compulsory licence by mandating that the licence note a "maximum quantity" of the product that is authorized for export. This quantity has to be specified in advance by the (lone) importing country (in its notification to the WTO) and the generic manufacturer (at the time of seeking the licence to export).¹⁹ This is unfortunate because increased needs and/or capacity to distribute additional drugs often cannot be correctly identified during the initial process to order the drug. Countries often have difficulties forecasting and updating the quantity of medicines needed to treat patients, particularly when available funding from different sources fluctuates. The one use of CAMR to date is illustrative: in its notification to the WTO of the expected quantity of the generic product to be imported from the Canadian generic manufacturer, Rwanda reserved the right to modify the expected quantity. Yet under CAMR as it stands, modification of the initial order outlined in the application for a compulsory licence is not permitted. To increase the order, the importing country, as well as the generic drug company that got the original compulsory licence to export their drug, would have to begin the process all over again and submit a new application for a second compulsory licence, even just to increase the quantity of the same drug already authorized for export to the same country.

Bill S-232 would eliminate this unnecessary limitation on the effective operation of CAMR: instead of requiring a separate licence (and hence licensing process) for any additional quantity of the medicine beyond the original "maximum quantity" authorized, the licence would continue to authorize the generic manufacturer to supply on an ongoing basis the changing quantities that eligible importing countries indicate they need.

TRIPS Article 31(c) says simply that "the scope and duration" of compulsory licensing "shall be limited to the purpose for which it was authorized"; this does not require that a compulsory licence include a specific limit on the quantity.

Nowhere does the 2003 WTO Decision require that Canada specify the "maximum quantity" of a product that may be exported under compulsory licence. The Decision *does* specify in paragraph 2(a)(i) that the importing country must notify the TRIPS Council of "the names and expected quantities of the product(s) needed." Clearly, "expected quantities" are just that — projections made as developing countries respond to evolving health needs, not an absolute limit ("maximum quantity") of a set number of pills. CAMR is more inflexible in restricting the scope of a compulsory licence than is required by the WTO Decision.

Furthermore, the WTO Decision's reference to "expected quantities" needed by importing countries does not require that a compulsory licence be limited to authorizing the export of just a specific quantity of a medicine. Rather, as is clear from paragraph 2(b)(i) of the WTO Decision, the exporting country must simply ensure that any compulsory licence issued 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". In other words, while

¹⁹ *Patent Act*, ss. 21.04(2)(c) and (3)(c).

there is some limit on the quantity that may be exported under a compulsory licence, that limit is determined by the importing countries' notifications of needs.

Bill S-232 does not substantively alter the current provisions in CAMR that ensure transparency and monitoring in the use of the system. Bill S-232 leaves intact the requirement that the generic licence-holder provide, within 15 days of entering into any agreement for the sale of the product authorized under a compulsory licence, a copy of said agreement to the Commissioner of Patents and to the patent-holders. In addition, the generic manufacturer must provide its sworn declaration (in a form prescribed by the Government pursuant to regulations under the Act) setting out both the total monetary value of the agreement (in Canadian currency) and also the quantity ("number of units") of the product to be sold under the agreement. Until this information is provided, the licence-holder is not permitted to export any of the product.²⁰ Furthermore, if this requirement is not met by the generic licence-holder, the patent-holder may seek a court order terminating the compulsory licence.²¹ This lets all parties know the quantity of the product the generic licence-holder is exporting and to which importing countries, and thus enables all parties to calculate the royalties that must be paid to the patent-holder(s) according to the existing formula in the CAMR regulations. If the licence-holder fails to pay any royalty, within the time required by the existing regulations, this too is grounds for terminating the compulsory licence.²²

In addition, the requirements in CAMR, pursuant to the 2003 WTO Decision, that a generic licence-holder post information about shipments on a website, remain largely intact. Bill S-232 *would* remove the current requirement that the generic manufacturer post the quantity of the product "that is authorized to be manufactured and sold for export" on the website it must maintain.²³ This is simply a consequential amendment following from the amendment (to s. 21.04) that eliminates the requirement that the compulsory licence itself specify in absolute terms the "maximum quantity" authorized for export: if the compulsory licence that is issued to the generic manufacturer does not note a specific quantity that is authorized for export, then it makes no sense to require that this non-existent quantity be posted on the website.

However, removing this requirement to post a specific quantity noted in the compulsory licence, does not mean that Bill S-232 contravenes the requirements of the 2003 WTO Decision. As noted above, the Decision requires that a compulsory licence be limited to supplying only those amounts of a generic medicine necessary to meet importing countries' identified needs. If an importing country has entered into an agreement with a Canadian generic manufacturer to purchase a certain quantity of a given medication, CAMR requires the generic manufacturer to provide a copy of that agreement and an additional statutory declaration, which sets out both the total value of the contract and the total number of units to be sold to the importing country, to both the patentee(s) and the Commissioner of Patents. The disclosure of the agreement and this sworn declaration, provided to the Government of Canada and the patent-holders, obviously establishes the quantities that the importing country has identified it needs. Bill S-232 preserves these disclosure obligations.

²⁰ *Patent Act*, s. 21.16, either in its current form or as amended by Bill S-232.

²¹ *Patent Act*, s. 21.14(e).

²² *Patent Act*, s. 21.14(d).

²³ *Patent Act*, s. 21.06(1).

For even greater clarity, in amending the *Patent Act* with Bill S-232 to streamline CAMR, Parliament could also insert the explicit requirement that a compulsory licence issued by the Commissioner of Patents must include the condition that the generic licence-holder “*is authorized to export the product to the extent necessary to meet the needs of importing countries or WTO Members, as notified to the Council for TRIPS in writing from time to time.*” This formulation would, obviously, include the quantity set out by way of the contract between the importing country and the generic manufacturer, a copy of which must be disclosed in any event by the generic manufacturer, as just noted above. This would make explicit what should already be clear *de facto*, including the required disclosure of importing countries and the quantities they have identified as necessary.

Conclusion: Canada is not prohibited by WTO law from allowing compulsory licences to issue without specifying a fixed maximum quantity of a product authorized for export, as long Canada’s legislation limits exports under a licence to the quantities identified by importing countries as necessary to address their public health problems.

4.3 Issuing one licence authorizing exports to more than one country

As noted, at the moment CAMR appears to require that a generic manufacturer obtain a separate licence — and hence pursue a separate licensing process of attempting to negotiate a voluntary licence and then applying for a compulsory licence — for each individual importing country to which it wishes to export a given product. Under Bill S-232, a single compulsory licence from the Commissioner of Patents will authorize export to any of the eligible importing countries named in the current lists of countries under the existing law. Such a process does not contravene any provision of the TRIPS Agreement or the 2003 WTO Decision — in fact, it is *more* in keeping with the spirit of both the 2001 Doha Declaration and the 2003 WTO Decision, which identify the need for an “expeditious solution” that affords developing countries a compulsory licensing mechanism that is a “rapid response” to address public health needs.

There is nothing in the TRIPS Agreement that limits a compulsory licence to authorizing exports to just a single country. As noted above, the 2001 Doha Declaration (paragraph 4) reaffirmed the right of WTO members to use “to the full” the flexibilities in the TRIPS Agreement to achieve the purpose of protecting public health “and, in particular, to promote access to medicines for all.” This directive points only the conclusion that the use of a tool such as compulsory licensing should be aimed at maximizing the benefit of access to medicines, not unnecessarily restricting a licence to benefiting just those in one country.

The 2003 WTO Decision repeatedly contemplates explicitly that a single compulsory licence could authorize exports of a generic pharmaceutical product to more than one country. Paragraph 2 refers specifically to “eligible importing Member(s)” in several places, clearly phrased in the plural. The chapeau of paragraph 2 specifically refers to “the grant by it [the exporting Member] of a compulsory licence” [*singular*] for purposes of producing “a pharmaceutical product(s)” and the export of that product to “an eligible importing Member(s)” [*again in the plural*]. More specifically, paragraph 2(b) states that “the compulsory licence” [*singular*] issued by the exporting Member shall contain the following conditions:

(i) the amount necessary to meet the needs of the “eligible importing Member(s) [plural] may be manufactured under the licence and the entirety of this product shall be exported to the Member(s) [plural] in question”

(ii) “products [plural] produced under the licence [singular] shall be clearly identified etc...”

(iii) before the generic manufacturer begins shipment, it must post on its website information about “the quantities being supplied to each destination as referred to” in paragraph 2(b)(i) [suggesting that there may be multiple destinations being supplied with different quantities pursuant to the single licence], and the distinguishing features of “the product(s)” [plural] referred to in paragraph 2(b)(i).

Furthermore, paragraph (2)(c) states that the exporting country’s notification to the TRIPS Council must include such information as “the product(s) [plural] for which the licence [singular] has been granted” and “the country(ies) [plural] to which the product(s) [plural] is(are) to be supplied and the duration of the licence [singular].”

In addition, the 2003 WTO Decision provides that, “with a view to harnessing economies of scale for the purposes of enhancing purchasing power for... pharmaceutical products”, a single compulsory licence can be used to supply multiple countries, via re-exportation from an original importing country, in the circumstances where the countries are parties to a regional trade agreement in which at least half of the member countries are “least-developed countries” (paragraph 6). WTO Members explicitly contemplated that the mechanism could and should be used to supply multiple countries via one arrangement, precisely because it would make good economic sense to do so.

Indeed, some other jurisdictions have not found it necessary to impose such the restriction of supplying only one country per licence. For example, the regulation adopted by the European Union to implement the 2003 WTO Decision refers to the generic manufacturer using the licence to supply “the importing country or countries.”²⁴

In sum, there is nothing in TRIPS or the 2003 WTO Decision that would preclude Canada from adopting legislation that allows for one compulsory licence to be issued that authorizes a generic manufacturer to export to more than one country. On the contrary, it seems to be explicitly contemplated on a plain-language reading of the text that this is permissible.

Conclusion: Canada is not prohibited by WTO law from issuing compulsory licences that authorize exportation of a generic pharmaceutical product to more than one country per licence. In the interests of a simple, rapid, flexible and efficient system, it would make sense for one licence issued under CAMR to permit the generic manufacturer to export to any of the countries that the law already deems eligible as recipient countries.

²⁴ “Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems”, *Official Journal of the European Union* (9 June 2006), pp. L157/1-7, Art. 6.3, at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00010007.pdf.

4.4 Removing the prerequisite of attempting to negotiate a voluntary licence

CAMR currently requires that a generic manufacturer first attempt to negotiate a voluntary licence with the patent-holder(s) before applying to the Commissioner of Patents for a compulsory licence. Bill S-232 would remove this requirement, allowing a generic manufacturer to apply directly to the Commissioner for a compulsory licence, which licence would include the condition that the generic manufacturer regularly remit royalties the patent-holder(s), according to the existing formula in the CAMR regulations, based on the agreements subsequently reached with various eligible importing countries and disclosed as required by the law).

The 2003 WTO Decision is confined to the mechanics and parameters of using a compulsory licence for exporting generic pharmaceuticals once said licence is issued; it says nothing specific regarding the question of negotiations for a voluntary licence before a compulsory licence is issued.

Rather, it is the provisions of the TRIPS Agreement that are relevant to this feature of Bill S-232. TRIPS Article 31(b) states that, in the ordinary course, compulsory licensing “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.” CAMR’s existing provisions already indicate that Canada considers 30 days to be a “reasonable period of time”,²⁵ and the existing formula for calculating the royalties payable to patent-holders already indicate what Canada considers to be “reasonable commercial terms and conditions”.²⁶

(a) TRIPS explicitly waives negotiation requirement in certain circumstances

While TRIPS Article 31(b) contains the general rule that negotiation is required as a precondition to compulsory licensing, Article 31(b) also states immediately following:

“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. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.”²⁷

WTO Members have also explicitly agreed in the 2001 Doha Declaration (paragraph 5(b)) that:

“Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises,

²⁵ *Patent Act*, s. 21.04(3)(c).

²⁶ “Use of Patented Products for International Humanitarian Purposes”, SOR/2005-143, s. 8.

²⁷ TRIPS Article 31(k) also waives the negotiation requirement in cases where a compulsory licence is issued “to remedy a practice determined after judicial or administrative process to be anti-competitive.”

including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”²⁸

Therefore, first and foremost, it must be observed that CAMR does not currently fully take advantage of even the flexibility already explicitly afforded by the TRIPS Agreement. As noted, the ordinary requirement to attempt negotiations with a patent-holder(s) before a compulsory licence may issue is automatically waived in urgent circumstances or in cases of “public non-commercial use.” In its current form, CAMR fails to reflect this, instead applying across the board its drug-order-by-drug-order, country-by-country process that requires attempted negotiation with patent-holder(s), even where this is not required by TRIPS. Recall that the bulk of generic medicines for AIDS or other health needs that could be imported by developing countries under a regime such as CAMR would be purchased for “public non-commercial use” in public hospitals or clinics or in not-for-profit clinics operated by humanitarian organizations. In such cases, CAMR should already dispense with the requirement to attempt negotiations for voluntary licences, allowing applications for compulsory licences (with royalty rates fixed by the existing formula). Insofar as Bill S-232 does away with the requirement of prior negotiation before compulsory licensing, in at least these very important circumstances there can be no doubt that it is entirely TRIPS-compliant because TRIPS itself already explicitly allows this requirement to be waived.

(b) Enacting streamlined regime allowing direct application for compulsory licence in all circumstances

Beyond the circumstances noted above in which TRIPS already explicitly allows for directly issuing a compulsory licence without any prior attempt at negotiating a voluntary licence, Bill S-232 would further streamline CAMR by allowing such a direct application for a licence to export to eligible importing countries as the standard procedure. Enhancing CAMR in this way is permissible under the TRIPS Agreement, for the reasons that follow. Recall that **WTO Members have repeatedly agreed that they each have latitude in how they interpret and implement their obligations under TRIPS** in their domestic laws, including when it comes to enacting a regime of compulsory licensing of patented pharmaceutical products for export.

- TRIPS Article 1(1) expressly states that WTO “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”²⁹ Furthermore, TRIPS Article 8 states that WTO “Members may, in formulating their laws and regulations, adopt measures necessary to protect public health . . . provided that such measures are consistent with the provisions of this Agreement.”

²⁸ More generally, it should be noted that the use of compulsory licensing under TRIPS is *not* limited to just emergencies or public health crises or epidemics (although the AIDS pandemic is certainly an ongoing global crisis); this is a common misconception, easily avoided by a plain reading of TRIPS Article 31(b). Furthermore, the wording of the 2001 Doha Declaration (paragraph 1) and the 2003 WTO Decision also make it clear that compulsory licensing of pharmaceuticals *for export* is not limited to just public health emergencies or epidemics.

²⁹ It should be noted that the Government of Canada, in its report of its review of CAMR, explicitly notes that “the possibility that divergent approaches toward implementing a particular trade rule can be equally compliant with the obligations in the TRIPS Agreement is not disputed”, citing TRIPS Article 1(1): *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act*, 14 December 2007, p. 29, online: http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport-eng.pdf .

- In the 2001 Doha Declaration (paragraphs 1-2), WTO members “stress[ed] the need for the . . . TRIPS Agreement to be part of the wider national and international action to address these problems” (i.e., public health problems afflicting developing and least-developed countries). As noted above, they also unanimously agreed (in paragraph 4):

“that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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.” [emphasis added]

- In addition, in the 2001 Doha Declaration, WTO members further reaffirmed that the flexibilities under TRIPS that can and should be used to the full to protect public health and promote access to medicines include the following: “Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted” (paragraph 5b). Furthermore WTO members expressly indicated (in paragraph 6) a particular concern for ensuring that countries lacking pharmaceutical manufacturing capacity be able to “make effective use of compulsory licensing” to import products needed to address public health problems from countries with the requisite manufacturing capacity. The 2003 WTO Decision is supposed to offer the “expeditious solution” to address this concern.
- The 2003 WTO Decision on which the current CAMR is based reaffirms the underlying flexibility that WTO Members enjoy as a matter of law in their interpretation and implementation of TRIPS. It states expressly (in paragraph 9):

This Decision is **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.

This statement, adopted unanimously by all WTO Members after more than 20 months of intensive negotiation, makes it explicitly clear that Members are not strictly limited to the confines of the 2003 WTO Decision in assisting countries with inadequate pharmaceutical manufacturing capacity make effective use of compulsory licensing, but rather can also draw upon other flexibilities provided for in TRIPS. It also is clear that the 2003 WTO Decision is without prejudice to the interpretation of those other provisions of TRIPS providing flexibility.

- Therefore, to legislate a streamlined compulsory licensing process that enables direct access to a compulsory licence, Canada can take advantage of other “flexibilities” open to it under TRIPS. In particular, **TRIPS Article 30 explicitly allows for WTO Members to legislate “limited exceptions” to exclusive patent rights:**

Exceptions to Rights Conferred

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.

- As is evident, this carefully-negotiated provision is worded in a very open-ended fashion, and affords important leeway to WTO members in implementing their other TRIPS obligations regarding granting exclusive patent rights. Under Article 30, Canada is free to enact “limited exceptions” to patent rights, including a streamlined process of compulsory licensing for export to developing countries that avoids the usual requirement of first attempting to negotiate a voluntary licence with the patent-holder(s).
- Given their repeated, unanimous statements on the matter, **WTO members clearly consider the health and lives of millions of poor patients in the developing world to be “legitimate interests of third parties” that can and should be taken into account** in crafting intellectual property regimes. Indeed, WTO Members themselves have engaged in this very exercise, from the 2001 Doha Declaration to the 2003 WTO Decision, the latter including the recognition that there may be other models as well and the declaration that it was adopted “without prejudice” to those others options.
- Furthermore, enacting a simplified compulsory licensing mechanism that removes the requirement of prior negotiation, as is proposed in Bill S-232, **cannot be considered to “unreasonably conflict with a normal exploitation of the patent” or to “unreasonably prejudice the legitimate interests of the patent owner”**. It creates an exception to exclusive patent rights of Canadian patent-holders solely for the limited purpose of exporting lower-cost generic medicines to developing countries with identified needs, an objective repeatedly and explicitly recognized by WTO Members as warranting such an exception. In doing so, it makes use of a measure that WTO members have repeatedly affirmed is part of the solution in addressing public health problems, and that each country has the right to use for this purpose, while precluding the supply of those lower-cost generics to high-income countries, from which patent-owners make the vast bulk of their profits through their exploitation of their patents. Obviously, WTO Members do not consider such a limitation on patent rights to either unreasonably conflict with patent-holders’ working of their patents or to unreasonably prejudice their interests.

Conclusion: WTO law does not prohibit Canada from removing the requirement of prior negotiation with a patent-holder(s) before a compulsory licence may issue. In fact, in the case of compulsory licences issued to address urgent circumstances, to supply generic medicines for public non-commercial use or to remedy anti-competitive practices, CAMR would be *more* TRIPS-compliant if it were to dispense with the current requirement for prior negotiation. As for other circumstances, the requirement of negotiation as a precondition to issuing a compulsory licence may also be removed; a regime that allows direct application for a compulsory licence constitutes a “legitimate exception” to otherwise exclusive patent rights and is therefore permissible under TRIPS, whose flexibilities may be used “to the full” to promote “access to medicines for all”.

5. Addressing other common misinformation and objections to proposed CAMR reforms

A number of specific objections have been raised to the reforms proposed in Bill S-232 that would make CAMR more workable for developing countries and generic pharmaceutical manufacturers. This has raised questions for some Parliamentarians. The Legal Network wishes to address each of those questions in turn, as those objections are without merit.

5.1 Bill S-232 preserves anti-diversion safeguards

It has been incorrectly suggested that Bill S-232 would remove all safeguards against diversion of medicines exported under compulsory licence.

During WTO negotiations, some member countries were concerned that generic drugs supplied under the 2003 WTO Decision could be diverted from the market for which they are intended and be sold to or in another country (and particularly high-income countries), instead of getting to the patients for whom the order was originally placed. Pharmaceutical companies provided little in the way of concrete examples of this occurring, and both before and since the 2003 WTO Decision there has been no evidence that this has been a significant problem.³⁰

Nevertheless, steps were taken to address the concern. Both the 2003 WTO Decision and CAMR contain anti-diversion measures that clearly distinguish between drugs made for export under legislation and brand-name drugs. These measures include: specific labelling; marking the generic drug with “XCL” to differentiate it from the brand-name product; and, as noted above, having the generic manufacturer create a website with information on the distinguishing features of the product, the quantity of the drug, and the country to which the drug is being exported. The generic company exporting the drug must also maintain and update the website every time a shipment leaves for the intended country.

Bill S-232 preserves the requirements for marking and labelling a generic medicine produced for export in a way that distinguishes it from the patented brand-name product sold in Canada, as

³⁰ K. Outterson, “Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets”, (2005) 1 *Yale Journal of Health Policy, Law and Ethics* 193-291 (at pp. 262-265). Outterson outlines how the only two widely-reported instances of alleged diversion of reduced-price antiretroviral (ARV) drugs were, upon further investigation, not substantiated as such by independent verification. In the first case, court proceedings in the United Kingdom unearthed that, notwithstanding Glaxo’s earlier representations: 99% of the drugs in question were not lower-cost medicines destined for charitable initiatives but rather ordinary commercial sales to Africa at prices approximating EU prices and in ordinary commercial packaging; the diversions occurred within Europe (likely France), not Africa; and in essence amount to legal parallel trade within the EU: *Glaxo Group Ltd. v. Dowelhurst Ltd.*, [2004] E.T.M.R. 39 (2003). In the second reported case, a local health group in Indonesia discovered some donated medicines had been diverted locally for resale on the illegal market or within public health clinics for more than the maximum legal amount. As Outterson notes: “This is a simple case of local corruption, and there is no evidence that the drugs were leaving the immediate market. This situation might be regrettable, but it is not dysfunctional arbitrage; it does not replace commercial markets in the high income countries”: *ibid.*, p. 264. Outterson observes that similar claims of diversion in Chile and Lebanon in the same report were “are sourced exclusively from local affiliates of PhRMA [Pharmaceutical Research and Manufacturers of America]. Neither report was substantiated; nor do they suggest dysfunctional arbitrage as opposed to local movement of drugs within low or medium income countries. In sum, empirical evidence to date does not indicate a sizable arbitrage market in ARVs from low income countries into the high income countries”: *ibid.*, pp. 264-5.

well as the requirements regarding disclosing and web-posting prescribed information, while making CAMR simpler to use and more effective.

In short, the over-stated concern about diversion of medicines has been addressed in the drafting of Bill S-232. It should not divert attention from the need for CAMR reform, nor is it a legitimate argument against streamlining CAMR.

5.2 Bill S-232 preserves and enhances options for reviewing quality of exported medicines

Requiring Health Canada approval of a generic manufacturer's product before granting a compulsory licence for export is an additional requirement under CAMR — specifically, *Food and Drugs Act* s. 37(2) — that is not mandated by the WTO Decision. (We also note that no other drugs manufactured in Canada require Health Canada approval for export: see *Food and Drugs Act*, s. 37(1). This requirement is mandated by law only for drugs produced under compulsory licence pursuant to the Regime. If the concern is to ensure the quality of drugs exported, then this distinction is arbitrary.)

In any event, Bill S-232 does *not* abolish the requirement that there be some sort of mechanism in CAMR to ensure review of medicines produced under compulsory licence for export. Rather, instead of mandating Health Canada review as the only such permissible mechanism, it adds other options for guaranteeing the quality of products being received by importing countries, and requires the use of (at least) one of the listed mechanisms. (See the new s. 38 to be added to the *Food and Drugs Act* by Bill S-232.)

For example, since many developing countries will require pre-qualification by the World Health Organization (WHO) of the generic product in question before purchasing it,³¹ requiring Health Canada approval of the generic manufacturer's product as an absolute precondition before the manufacturer can get a compulsory licence can lead to duplication of effort and add unnecessary delay. (The WHO's Prequalification Programme operates in part with technical support from Health Canada.)

Some countries may also wish to have their own drug regulatory authority approve the product, although this could well be a minority of developing countries that might use the Regime to obtain lower-cost generic products, given the costs associated with maintaining such a regulatory capacity. Other importing countries may be content to accept the approval granted by a drug regulatory authority in certain countries with recognized standards of review, such as Canada. It should be within the purview of the importing country, and not the Government of Canada, to determine the regulatory review process on which it wishes to base procurement decisions.

As part of assisting developing countries in obtaining lower-cost medicines of reliable quality, not only does Bill S-232 preserve Health Canada approval as one option for guaranteeing the quality of a drug produced under CAMR for export, it also *requires* Health Canada to provide this review if the generic manufacturer seeking to export the product requests it.

³¹ For information about WHO's Prequalification Programme, see: <http://mednet3.who.int/prequal/>.

6. Conclusion

In the form of CAMR, Canada has implemented the mechanism embodied in the 2003 WTO Decision. So far, Canada's model cannot be considered a success — and the WTO Decision has not yet worked in any other country where it has been implemented. Canada was one of the first countries to implement the WTO Decision with a complete legislative framework, and it is the jurisdiction in which the most concerted efforts have been made to date to use the mechanism. As such, Canada is in a position to set a positive global precedent by implementing a better, TRIPS-compliant model that will engage generic pharmaceutical manufacturers and developing -country purchasers in increasing access to more affordable treatment for people in desperate need in many developing countries.

Bill S-232 represents such a model. It is simpler, clearer, easier to understand, more direct, more flexible, more efficient, and complies with Canada's obligations as a WTO member. Bill S-232 preserves some of the positive features of the current CAMR, while streamlining the process for compulsory licensing in ways that still comply with TRIPS and with the 2003 WTO Decision that underlies CAMR. Bill S-232 does not conflict with the 2003 WTO Decision, which in any event is "without prejudice" to other mechanisms that make use of recognized flexibilities under TRIPS. WTO Members have affirmed, in the 2001 Doha Declaration, that such flexibilities, including but not limited to compulsory licensing, may be used "to the full" to promote "access to medicines for all". The one-licence solution proposed in Bill S-232 would permit the "rapid response" that WTO members recognized, in the 2003 WTO Decision, is needed — but which, unfortunately, has so far not resulted from Canada's implementation of that Decision.

Bill S-232 would help Canada deliver on Parliament's unanimous pledge, made more than 6 years ago, to help poor people gain access to medicines in the developing world. The promise need not be broken.

Appendix:

Bill S-232 amendments to the *Patent Act* and the *Foods and Drugs Act*

PATENT ACT, R.S.C. 1985, c. P-4

USE OF PATENTS FOR INTERNATIONAL HUMANITARIAN PURPOSES TO ADDRESS PUBLIC HEALTH PROBLEMS

Purpose

21.01 The purpose of sections 21.02 to ~~21.16~~ 21.2 is to ~~give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating~~ access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2004, c. 23, s. 1.

Definitions

21.02 The definitions in this section apply in ~~this section and~~ in sections ~~21.01~~ 21.03 to ~~21.16~~ 21.19.

"authorization"

« *autorisation* »

"authorization" means an authorization granted under subsection 21.04(1), ~~and includes an authorization renewed under subsection 21.12(1).~~

"General Council"

« *Conseil général* »

"General Council" means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

"General Council Decision"

« *décision du Conseil général* »

"General Council Decision" means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson's statement of that date.

"patented product"
« ~~produit breveté~~ »

"patented product" means a product the making, constructing, using or selling of which in Canada would infringe a patent in the absence of the consent of the patentee.

"pharmaceutical product"
« ~~produit pharmaceutique~~ »

"pharmaceutical product" means any drug, as defined in section 2 of the *Food and Drugs Act*, and includes monitoring products and products used in conjunction with a pharmaceutical product. ~~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.~~

"TRIPS Agreement"
« ~~Accord sur les ADPIC~~ »

"TRIPS Agreement" means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

"TRIPS Council"
« ~~Conseil des ADPIC~~ »

"TRIPS Council" means the council referred to in the TRIPS Agreement.

"WTO"
« ~~OMC~~ »

"WTO" means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

2004, c. 23, s. 1.

Amending Schedules

21.03 (1) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend the Schedule to add the name of a country if the country is

(a) recognized by the United Nations as being a least-developed country; or

(b) named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance.

~~(a) on the recommendation of the Minister and the Minister of Health, amend Schedule 4~~

~~(i) by adding the name of any patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by~~

~~adding one or more of the following in respect of the patented product, namely, a dosage form, a strength and a route of administration, and~~

~~(ii) by removing any entry listed in it;~~

~~(b) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 2 by adding the name of any country recognized by the United Nations as being a least-developed country; that has,~~

~~(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, and~~

~~(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;~~

~~(c) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision; and~~

~~(d) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 4 by adding the name of~~

~~(i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, or~~

~~(ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance and that has provided the Government of Canada with a notice in writing through diplomatic channels~~

~~(A) stating that it is faced with a national emergency or other circumstances of extreme urgency,~~

~~(B) specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency,~~

~~(C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and~~

~~(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.~~

Restriction – Schedule 3

~~(2) The Governor in Council may not add to Schedule 3 the name of any WTO Member that has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency.~~

Removal from Schedules 2 to 4

(3) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend any of the Schedules 2 to 4 to remove the name of a any country or WTO Member if the country is neither

(a) recognized by the United Nations as being a least-developed country; nor

(b) named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance.

~~(a) in the case of a country or WTO Member listed in Schedule 2, the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or, in the case of a country that is not a WTO Member, the country has permitted any product imported into that country under an authorization to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision;~~

~~(b) in the case of a WTO Member listed in Schedule 3, the WTO Member has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency;~~

~~(c) in the case of a WTO Member listed in Schedule 4, the WTO Member has revoked any notification it has given to the TRIPS Council that it will import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, only if faced with a national emergency or other circumstances of extreme urgency;~~

~~(d) in the case of a country listed in Schedule 4 that is not a WTO Member,~~

~~(i) the name of the country is no longer on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance;~~

~~(ii) the country no longer faces a national emergency or other circumstances of extreme urgency;~~

~~(iii) the country has permitted any product imported into that country under an authorization to be used for commercial purposes, or~~

~~(iv) the country has failed to adopt the measures referred to in Article 4 of the General Council Decision;~~

~~(e) in the case of any country or WTO Member listed in Schedule 3 or 4, the country or WTO Member has become recognized by the United Nations as a least developed country; and~~

~~(f) in the case of any country or WTO Member listed in any of Schedules 2 to 4, the country has notified the Government of Canada, or the WTO Member has notified the TRIPS Council, that it will not import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision.~~

Timeliness of orders

(4) An order under this section shall be made in a timely manner.

2004, c. 23, s. 1.

Authorization

21.04 (1) Subject to subsections (3) and (4), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to

(a) manufacture the pharmaceutical product or products named in the application;

(b) make, construct and use any a patented invention solely for the purposes directly related to the manufacture of of manufacturing the pharmaceutical product or products named in the application; and

(c) to sell the product or products it for export to a country or WTO Member that is listed in the Schedule. any of Schedules 2 to 4 and that is named in the application.

(1.1) In addition to what is authorized under subsection (1), an authorization under that subsection authorizes the person to

(a) manufacture any active ingredient used in the manufacture of a finished product; and

(b) make, construct and use any patented invention solely for the purpose of manufacturing any active ingredient used in the manufacture of a finished product.

(1.2) If a country is removed from the Schedule an authorization continues to apply with respect to that country for 30 days as though that country had not been removed from the Schedule.

Contents of application

(2) The application must be in the prescribed form and set out

(a) the name of the pharmaceutical product to be manufactured and sold for export under the authorization; and

~~(b) prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization;~~

~~(c) the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;~~

~~(d) for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued in respect of that invention;~~

~~(e) the name of the country or WTO Member to which the pharmaceutical product is to be exported;~~

~~(f) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and~~

(g) any other information that may be prescribed.

Conditions for granting of authorization

(3) The Commissioner shall grant an authorization ~~authorize the use of the patented invention only if~~

~~(a) the applicant has complied with the prescribed requirements, if any;~~

~~(b) the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements of the *Food and Drugs Act* and its regulations, including the requirements under those regulations relating to the marking, embossing, labelling and packaging that identify that version of the product as having been manufactured~~

~~(i) in Canada as permitted by the General Council Decision, and~~

~~(ii) in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by, or with the consent of, the patentee or patentees, as the case may be;~~

~~(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least thirty days before filing the application,~~

~~(i) 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 the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful, and~~

~~(ii) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(a) to (g); and~~

~~(d) the applicant also provides the Commissioner with~~

~~(i) if the application relates to a WTO Member listed in Schedule 2, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and~~

~~(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that WTO Member, or~~

~~(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,~~

~~(ii) if the application relates to a country listed in Schedule 2 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country, and~~

~~(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that country, or~~

~~(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product,~~

~~(iii) if the application relates to a WTO Member listed in Schedule 3, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and~~

~~(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or~~

~~(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,~~

~~(iv) if the application relates to a WTO Member listed in Schedule 4, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member is faced with a national emergency or other circumstances of extreme urgency and that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and~~

~~(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or~~

~~(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product, or~~

~~(v) if the application relates to a country listed in Schedule 4 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country, and stating that it is faced with a national emergency or other circumstances of extreme urgency, that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, that it agrees that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision, and~~

~~(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that country, or~~

~~(B) a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product.~~

(4) The Commissioner may refuse to grant an authorization if, in the opinion of the Commissioner, the authorization would not further the purpose set out in section 21.01.

2004, c. 23, s. 1.

Form and content of authorization

21.05 (1) The authorization must be in the prescribed form and, ~~subject to subsection (2),~~ contain the prescribed information.

Quantity

~~(2) The quantity of the product authorized to be manufactured by an authorization may not be more than the lesser of~~

~~(a) the maximum quantity set out in the application for the authorization, and~~

~~(b) the quantity set out in the notice referred to in any of subparagraphs 21.04(3)(d)(i) to (v), whichever is applicable.~~

21.051 The holder of an authorization shall ensure that all products manufactured under the authorization are labelled in accordance with the prescribed requirements.

2004, c. 23, s. 1.

Disclosure of information on website

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 country ~~or WTO Member~~ to which it is to be exported, ~~the quantity that is authorized to be manufactured and sold for export and the distinguishing features of the product, and of its label and packaging, as required by regulations made under the Food and Drugs Act, as well as information identifying every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported.~~

Obligation to maintain

(2) The holder must maintain the website during the entire period during which the authorization is valid.

Links to other websites

(3) The Commissioner shall post and maintain on the website of the Canadian Intellectual Property Office a link to each website required to be maintained by the holder of an authorization under subsection (1).

Posting on the website

(4) The Commissioner shall, within seven days of receipt, post on the website of the Canadian Intellectual Property Office each application for authorization filed under subsection 21.04(1).

2004, c. 23, s. 1.

Export notice

21.07 Before each shipment of any quantity of a product manufactured under an authorization, the holder of the authorization must, within fifteen days before the product is exported, provide to each of the following a notice, by certified or registered mail, specifying the quantity to be exported, as well as every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported:

- (a) the patentee or each of the patentees, as the case may be;
- (b) the country or WTO Member named in the authorization; and
- (c) the person or entity that purchased the product to which the authorization relates.

2004, c. 23, s. 1.

Royalty

21.08 (1) Subject to subsections (3) and (4), on the occurrence of a prescribed event, the holder of an authorization is required to pay to the patentee or each patentee, as the case may be, a royalty determined in the prescribed manner.

Factors to consider when making regulations

(2) In making regulations for the purposes of subsection (1), the Governor in Council must consider the humanitarian and non-commercial reasons purposes underlying the issuance of authorizations under subsection 21.04(1).

Time for payment

(3) The royalties payable under this section must be paid within the prescribed time.

Federal Court may determine royalty

(4) The Federal Court may, in relation to any authorization, make an order providing for the payment of a royalty that is greater than the royalty that would otherwise be required to be paid under subsection (1).

Application and notice

(5) An order may be made only on the application of the patentee, or one of the patentees, as the case may be, and on notice of the application being given by the applicant to the holder of the authorization.

Contents of order

(6) An order may provide for a royalty of a fixed amount or for a royalty to be determined as specified in the order, and the order may be subject to any terms that the Federal Court considers appropriate.

Conditions for making of order

~~(7) The Federal Court may make an order only if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration for the use of the invention or inventions to which the authorization relates, taking into account~~

~~(a) the humanitarian and non-commercial reasons underlying the issuance of the authorization; and~~

~~(b) the economic value of the use of the invention or inventions to the country or WTO Member.~~

2004, c. 23, s. 1.

Duration

21.09 ~~An authorization granted under subsection 21.04(1) is valid for a period of two years beginning on the day on which the authorization is granted. until either~~

~~a) the authorization is terminated by the Federal Court in accordance with the provisions of this Act; or~~

~~b) the expiry of any relevant patent or patents that would otherwise impede the holder of the authorization from making, constructing or otherwise using a patented invention for purposes of manufacturing the pharmaceutical product or products named in the authorization and exporting it to a country or WTO Member named in the Schedule.~~

2004, c. 23, s. 1.

Use is non-exclusive

21.1 The use of a patented invention under an authorization is non-exclusive.

2004, c. 23, s. 1.

Authorization is non-transferable

21.11 An authorization is non-transferable, other than where the authorization is an asset of a corporation or enterprise and the part of the corporation or enterprise that enjoys the use of the authorization is sold, assigned or otherwise transferred.

2004, c. 23, s. 1.

Renewal

21.12 ~~(1) The Commissioner shall, on the application of the person to whom an authorization was granted and on the payment of the prescribed fee, renew the authorization if the person certifies under oath in the renewal application that the quantities of the pharmaceutical product authorized to be exported were not exported before the authorization ceases to be valid and~~

~~that the person has complied with the terms of the authorization and the requirements of sections 21.06 to 21.08.~~

One renewal

~~(2) An authorization may be renewed only once.~~

When application must be made

~~(3) The application for renewal must be made within the 30 days immediately before the authorization ceases to be valid.~~

Duration

~~(4) An authorization that is renewed is valid for a period of two years beginning on the day immediately following the day of the expiry of the period referred to in section 21.09 in respect of the authorization.~~

Prescribed form

~~(5) Applications for renewal and renewed authorizations issued under subsection (1) must be in the prescribed form.~~

~~2004, c. 23, s. 1.~~

Termination

21.13 (1) A holder of an authorization may relinquish the authorization by giving written notice to the Commissioner.

(2) The authorization ceases to be valid when notice is given to the Commissioner under subsection (1).

(3) If an authorization in respect of a patentee's invention is relinquished, the Commissioner shall, without delay, notify the patentee in writing.

~~Subject to section 21.14, an authorization ceases to be valid on the earliest of~~

~~(a) the expiry of the period referred to in section 21.09 in respect of the authorization, or the expiry of the period referred to in subsection 21.12(4) if the authorization has been renewed, as the case may be,~~

~~(b) the day on which the Commissioner sends, by registered mail, to the holder of the authorization a copy of a notice sent by the Minister of Health notifying the Commissioner that the Minister of Health is of the opinion that the pharmaceutical product referred to in that authorization paragraph 21.04(3)(b) has ceased to meet the requirements set out in section 37(3) of the Food and Drugs Act and its regulations,~~

~~(c) the day on which the last of the pharmaceutical product authorized by the authorization to be exported is actually exported,~~

~~(d) thirty days after the day on which~~

~~(i) the name of the pharmaceutical product authorized to be exported by the authorization is removed from Schedule 1, or~~

~~(ii) the name of the country or WTO Member to which the pharmaceutical product was, or is to be, exported is removed from the Schedule 2, 3 or 4, as the case may be, and not added to any other of those Schedules, and~~

~~(e) on any other day that is prescribed.~~

2004, c. 23, s. 1.

Termination by Federal Court

21.14(1) On the application of a patentee, and on notice given by the patentee to the person to whom an authorization was granted, the Federal Court may make an order, on any terms that it considers appropriate, terminating the authorization if the patentee establishes that

~~(a) the application for the authorization or any of the documents provided to the Commissioner in relation to the application contained any material information that is inaccurate;~~

~~(a) the holder of the authorization has failed to comply with section 21.051;~~

~~(b) the holder of the authorization has failed to establish a website as required by section 21.06, has failed to disclose on that website the information required to be disclosed by that section or has failed to maintain the website as required by that section;~~

~~(c) the holder of the authorization has failed to provide a notice required to be given under section 21.07;~~

~~(d) the holder of the authorization has failed to pay, within the required time, any royalty required to be paid as a result of the authorization;~~

~~(e) the holder of the authorization has failed to comply with subsection 21.16(2);~~

~~(f) the product exported to the country or WTO Member, as the case may be, under the authorization has been, with the consent knowledge of the holder of the authorization, re-exported in a manner that is contrary to the General Council Decision to a country that is not listed in the Schedule; or.~~

~~(i) appears on the Schedule of countries and WTO members to which export is permitted under an authorization obtained under this Act, or~~

~~(ii) is a party to a regional trade agreement with other countries at least half of whom are least developed countries in a manner that is contrary to the General Council Decision;~~

(g) the product was exported, other than in the normal course of transit, to a country that is not listed in the Schedule, or WTO Member other than one that

(i) appears on the Schedule of countries and WTO members to which export is permitted under an authorization obtained under this Act, or

(ii) is a party to a regional trade agreement with other countries at least half of whom are least developed countriesthe country or WTO Member named in the authorization;

(h) the product was exported in a quantity greater than the quantity authorized to be manufactured; or

~~(i) if the product was exported to a country that is not a WTO Member, the country has permitted the product to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision.~~

(2) Paragraph (1)(g) does not apply if a product is exported to a party to a relevant regional trade agreement that is not listed in the Schedule for re-export to parties to the agreement that are listed in the Schedule; and

(3) An agreement is a relevant regional trade agreement for the purposes of subsection (2) if

(a) at least half the parties to the agreement are listed in the Schedule; and

(b) the agreement provides for trade in the product.

2004, c. 23, s. 1.

Notice to patentee

21.15 The Commissioner shall, without delay, notify the patentee, or each of the patentees, as the case may be, in writing of any authorization granted in respect of the patentee's invention.

2004, c. 23, s. 1.

Obligation to provide copy of agreement

21.16 (1) Within fifteen days after entering into an ~~the later of the day on which the authorization was granted and the day on which the~~ agreement for the sale of the product to which the authorization relates ~~was entered into~~, the holder of an authorization must provide by certified or registered mail, the Commissioner and the patentee, or each patentee, as the case may be, with

(a) a copy of the agreement; ~~it has reached with the purchaser person or entity referred to in paragraph 21.04(2)(f) for the supply of the product authorized to be manufactured and sold,~~ which agreement must incorporate information that is in all material respects identical to the information referred to in paragraphs 21.04(2)(a), (b), (e) and (f); and

(b) a solemn or statutory declaration in the prescribed form setting out

- (i) the total monetary value of the agreement as it relates to the product authorized to be manufactured and sold, expressed in Canadian currency, and
- (ii) the number of units of the product to be sold under the terms of the agreement.

Prohibition

(2) The holder of an authorization may not export any product to which the authorization relates until after the holder has complied with subsection (1).

2004, c. 23, s. 1.

Application when agreement is commercial in nature

~~**21.17** (1) If the average price of the product to be manufactured under an authorization is equal to or greater than 25 per cent of the average price in Canada of the equivalent product sold by or with the consent of the patentee, the patentee may, on notice given by the patentee to the person to whom an authorization was granted, apply to the Federal Court for an order under subsection (3) on the grounds that the essence of the agreement under which the product is to be sold is commercial in nature.~~

Factors for determining whether agreement is commercial in nature

~~(2) In determining whether the agreement is commercial in nature, the Federal Court must take into account~~

- ~~(a) the need for the holder of the authorization to make a reasonable return sufficient to sustain a continued participation in humanitarian initiatives;~~
- ~~(b) the ordinary levels of profitability, in Canada, of commercial agreements involving pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision; and~~
- ~~(c) international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes.~~

Order

~~(3) If the Federal Court determines that the agreement is commercial in nature, it may make an order, on any terms that it considers appropriate,~~

- ~~(a) terminating the authorization; or~~
- ~~(b) requiring the holder to pay, in addition to the royalty otherwise required to be paid, an amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent.~~

Additional order

~~(4) If the Federal Court makes an order terminating the authorization, the Federal Court may also, if it considers it appropriate to do so, make an order, on any terms that it considers appropriate,~~

~~(a) requiring the holder to deliver to the patentee any of the product to which the authorization relates remaining in the holder's possession as though the holder had been determined to have been infringing a patent; or~~

~~(b) with the consent of the patentee, requiring the holder to export any of the product to which the authorization relates remaining in the holder's possession to the country or WTO Member named in the authorization.~~

Restriction

~~(5) The Federal Court may not make an order under subsection (3) if, under the protection of a confidentiality order made by the Court, the holder of the authorization submits to a Court-supervised audit and that audit establishes that the average price of the product manufactured under the authorization does not exceed an amount equal to the direct supply cost of the product plus 15 per cent of that direct supply cost.~~

Definitions

~~(6) The following definitions apply in this section.~~

~~"average price"~~

~~«prix moyen»~~

~~"average price" means~~

~~(a) in relation to a product to be manufactured under an authorization, the total monetary value of the agreement under which the product is to be sold, expressed in Canadian currency, divided by the number of units of the product to be sold under the terms of the agreement; and~~

~~(b) in relation to an equivalent product sold by or with the consent of the patentee, the average of the prices in Canada of that product as those prices are reported in prescribed publications on the day on which the application for the authorization was filed.~~

~~"direct supply cost"~~

~~«coût direct de fourniture»~~

~~"direct supply cost", in relation to a product to be manufactured under an authorization, means the cost of the materials and of the labour, and any other manufacturing costs, directly related to the production of the quantity of the product that is to be manufactured under the authorization.~~

~~"unit"~~

~~«unité»~~

~~"unit", in relation to any product, means a single tablet, capsule or other individual dosage form of the product, and if applicable, in a particular strength.~~

2004, c. 23, s. 1.

Advisory committee

~~21.18~~ (1) The Minister and the Minister of Health shall establish, within three years after the day this section comes into force, an advisory committee to advise them on the recommendations that they may make to the Governor in Council respecting the amendment of Schedule 1.

Standing committee

~~(2) The standing committee of each House of Parliament that normally considers matters related to industry shall assess all candidates for appointment to the advisory committee and make recommendations to the Minister and the Minister of Health on the eligibility and qualifications of those candidates.~~

2004, c. 23, s. 1; 2005, c. 18, s. 1.

Website for notices to Canada

~~21.19~~ The person designated by the Governor in Council for the purpose of this section must maintain a website on which is set out a copy of every notice referred to in subparagraphs 21.04(3)(d)(ii) and (v) that is provided to the Government of Canada through diplomatic channels by a country that is not a WTO Member. The copy must be added to the website as soon as possible, and within at most fifteen days, after the notice has been provided to the Government of Canada.

2004, c. 23, s. 1.

Review

~~21.2~~ (1) A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force.

Tabling of report

~~(2) The Minister must cause a report of the results of the review to be laid before each House of Parliament on any of the first fifteen days on which that House is sitting after the report has been completed.~~

2004, c. 23, s. 1.

* * * * *

FOOD AND DRUGS ACT, R.S.C. 1985, c. F-27

EXPORTS

Conditions under which exports exempt

37. (1) This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word “Export” or “Exportation” and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.

Exception - General Council Decision

(2) This section does not apply with respect to a product manufactured or sold under an authorization granted under subsection 21.04(1) of the *Patent Act*.

~~(2) Despite subsection (1), this Act applies in respect of any drug or device to be manufactured for the purpose of being exported in accordance with the General Council Decision, as defined in subsection 30(6), and the requirements of the Act and the regulations apply to the drug or device as though it were a drug or device to be manufactured and sold for consumption in Canada, unless the regulations provide otherwise.~~

38. (1) This section applies with respect to a product manufactured or sold under an authorization granted under subsection 21.04(1) of the *Patent Act*.

(2) Part 1 does not apply with respect to a product described in subsection (1).

(3) No person shall export a product described in subsection (1) unless one of the following requirements is satisfied:

- (a) the Minister has confirmed, in writing, that the product meets the requirements that would be applicable under this Act if Part 1 applied with respect to the product;
- (b) the drug regulatory authority of the country to which the product is to be exported has given written approval of the product;
- (c) a drug regulatory authority of another jurisdiction has given written approval of the product and the government of the country to which the product is to be exported, in writing, that such approval is satisfactory;
- (d) a drug regulatory authority of another jurisdiction has given written approval of the product and the Minister has indicated, in writing, that in the Minister's view the requirements applied by that authority are at least as stringent as the requirements under this Act; or
- (e) the product has been approved, in writing, under the Prequalification Programme of the World Health Organization.

(4) Upon request by a person who has filed or intends to file an application for an authorization under subsection 21.04(1) of the *Patent Act* with respect to a product, the Minister shall determine whether the product meets the requirements that would be applicable under this Act if Part 1 applied with respect to the product.

R.S., 1985, c. F-27, s. 37; 1993, c. 34, s. 73; 1996, c. 19, s. 80; 2004, c. 23, s. 3.