



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

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Summary

Canada's Access to Medicines Regime is not delivering on the country's pledge to help developing countries get affordable medicines. The Canadian HIV/AIDS Legal Network recommends a number of changes that will help fix the current, flawed Regime:

- Streamline the compulsory licensing process, by giving broader legal authorization upfront to manufacture generic medicines for export, instead of limiting the authorization to fulfilling only a single order for a single country after a cumbersome process. This could be done easily by amending the *Patent Act* to include a section authorizing the manufacture of generic versions of any pharmaceutical product patented in Canada for export to any eligible country specified in the legislation. Alternatively, a manufacturer could be granted a single, open-ended licence on a given drug that authorizes the exportation of that drug to any eligible country specified in the legislation. Such an approach is different from the 2003 WTO Decision on which Canada's current law is based, but is permissible under WTO rules. With either mechanism,
 - the authorization would not be limited to exporting a predetermined quantity of a product to a single country, and would not require a new application process for every single (tentative) contract negotiated between a generic manufacturer and a potential purchaser;
 - there would be no need to reveal the name of a would-be developing-country purchaser (which exposes the country to pressure from governments or corporations opposed to compulsory licensing) before it is even certain that a drug can be exported by a generic manufacturer in Canada;
 - a generic manufacturer would be required to remit periodically to the patent-holder(s) royalties payable, which can be determined according to the existing formula in the Regime.
- Eliminate the requirement to first attempt negotiating for a voluntary licence from a patent-holder, particularly in cases where generic medicines are being supplied in cases of emergencies, for public non-commercial use, and for remedying anti-competitive practices by patent-holders.
- Make it easier for NGOs to purchase Canadian-made generics, by eliminating the requirement that they obtain the "permission" of the importing country government.
- Treat non-WTO developing countries fairly, by eliminating the additional requirements for becoming eligible to import Canadian-made generics — restrictions that do not apply to developing countries that belong to the WTO.
- Eliminate the limited list of products that can be made in generic form for export.
- Accept alternatives to Health Canada approval of a generic product, such as prequalification by the World Health Organization, as a precondition to exporting the product.
- Eliminate the arbitrary and counter-productive limit of two years on the length of an authorization to export a generic drug.
- Eliminate the provisions that give patent-holders extra, and unnecessary opportunities for vexatious litigation aimed at deterring use of the Regime.

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 Canada's leading advocacy organization working on the legal and human rights issues raised by HIV/AIDS.

The Legal Network is a national non-governmental organization with over 200 members across Canada and around the world. It was actively involved in discussions leading up to the passage of the legislation that established what is now referred to as "Canada's Access to Medicines Regime." The Legal Network provided 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.

2. Background to Canada's Access to Medicines Regime

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" ("the Regime"). This legislative scheme is supposed 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 drugs and also lack the domestic capacity to manufacture generic drugs.

Canada's legislation came into force in May 2005; the accompanying regulations came into effect in June 2005. However, despite concerted efforts, to date not a single pill has been exported under the Regime. As recognized by the government in its recent consultation paper, the Regime is failing to meet its goals.¹ Similarly, the Senate Standing Committee on Foreign Affairs and International Trade has recently recommended that Canada should "amend Canada's Access to Medicines Regime, including its underlying legislation, to make it more effective in prompting shipments of medications for HIV/AIDS sufferers to Africa,"² (though it should be noted that the Regime extends beyond addressing AIDS in Africa).

The possible use of the Regime is influenced by a variety of larger political and economic factors, including the pressure that developing countries face, and have faced for years,

¹ Government of Canada, "Canada's Access to Medicines Regime – Consultation Paper", 11 November 2006, on-line: <http://camr-rcam.hc-sc.gc.ca>.

² Senate Standing Committee on Foreign Affairs and International Trade, "Overcoming 40 Years of Failure: A New Road Map for Sub-Saharan Africa", February 2007, at p. 117, on-line: <http://www.parl.gc.ca/39/1/parlbus/commbus/senate/com-e/fore-e/rep-e/repafriFeb07-e.pdf>.

from some high-income countries — in particular the United States — to refrain from taking measures such as compulsory licensing to obtain lower-cost pharmaceutical products.

Canada cannot, through legislation, address all of the factors that may dissuade developing countries from taking advantage of policy options such as compulsory licensing to obtain less expensive medicines. But the Government and Parliament can craft our legislative regime to take account of this political reality and of the practical considerations that face both generic manufacturers and developing countries as the producers and procurers, respectively, of medicines that could be manufactured under compulsory licences.

The Regime has not yet delivered on its 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 parliamentarians should not to limit the current review to solely making small adjustments to the Regime; the central objective must be to fix the Regime's current unwieldy process for authorizing the production of generic pharmaceuticals for export to eligible countries.

Our central recommendation, below, would replace the existing process for obtaining a compulsory licence with something considerably 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 (WTO). We also recommend a number of additional reforms that would eliminate some of the unnecessary and counterproductive features currently hindering the efficacy of the Regime; some of these changes would be moot if the compulsory licensing mechanism we recommend were to be adopted, while others are relevant to whichever mechanism appears in Canada's law.

3. Reforming Canada's Access to Medicines Regime

(a) Streamline the compulsory licensing process

- ***Current process is cumbersome and unrealistic***

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. However, TRIPS Article 31(f) previously restricted the use of compulsory licensing to authorize the production of generics for export, stating that any use of a patented invention could only be authorized "predominantly for the supply of the domestic market of the Member authorizing such use". On August 30, 2003, ostensibly in the interests of public health, the WTO General Council unanimously adopted a decision that waived this restriction ("WTO Decision").³

³ 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, on-line: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

WTO members declared that this 2003 Decision, on which Canada's Access to Medicines Regime and the regimes of a handful of other countries is based, 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. To date, one would-be producer, Apotex Inc., and one would-be purchaser, Médecins Sans Frontières (MSF), have attempted to use the Regime to produce and export a lower-cost generic version of a fixed-dose combination antiretroviral drug (ARV) to treat people living with HIV/AIDS in the developing world through MSF treatment projects. Those efforts began in May 2004, shortly after the legislation was enacted by Parliament. Yet this experience has illustrated that the mechanism set out in the WTO Decision, and enacted in Canada, is "neither expeditious, nor a solution".⁴

Canada was one of the first countries to implement a detailed legislative regime for implementing the WTO Decision. A number of other jurisdictions — Norway, the Netherlands, India, South Korea, China, and the European Union — have also adopted legislation, regulations or other instruments that in some way, with varying degrees of specificity and latitude, implement the WTO Decision to permit compulsory licensing of patented pharmaceuticals for export to certain eligible countries.⁵ However, as with Canada's regime, there have not yet been any exports. Furthermore, almost four years after the WTO Decision was adopted, not a single country has yet made the requisite notification to the WTO of its intent to use the mechanism set out in the Decision to import generic medicines from another country, notwithstanding the undeniable, widespread need for more affordable medicines.⁶

This experience suggests that there is a fundamental problem with the mechanism set out in the WTO Decision itself. The mechanism, embodied in Canada's law, ignores the realities of both generic drug manufacturers and developing countries. Developing

⁴ 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, on-line: www.accessmed-msf.org/documents/WTOaugustreport.pdf

⁵ Norway: *Act of 19 December 2003 No. 127* (amending *Act of 15 December 1967 No. 9* relating to patents), and *Royal Decree of 14 May 2004* (amending Patent Regulations of 20 December 1996 No. 1162), in WTO Doc. IP/C/W/427 (17 September 2004); Netherlands: "Policy Rules on issuing compulsory licences under s. 57(1) of the *Kingdom Act on Patents of 1995*", *State Gazette*, 21 December 2004; India: *The Patents (Amendment) Act, 2005*, No. 15 of 2005; Korea: *Korean Patent Act* as revised by Industry and Energy Committee of the National Assembly (enacted 31 May 2005, effective 1 December 2005); China: Order #37 of the State Intellectual Property Office – "Measures to Implement Public Health-Related Compulsory Licensing" (effective 1 January 2006) [unofficial translation]; European Union: *Regulation (EC) No. 816/2006 of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems* (entered into force 9 June 2006); all on-line via: www.cptech.org/ip/wto/p6/index.html. In addition, Switzerland has drafted a proposed amendment to its federal patent law, on-line: <http://www.ige.ch/E/jurinfo/documents/j10019e.pdf>.

⁶ See the dedicated webpage on the WTO website for such notifications at www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

countries need simple contract processes that will ensure sustainable supplies of essential medicines or other pharmaceutical products; these contracts must be flexible enough to adjust to changing needs.

The WTO Decision as enacted by Canada, however, forces generic manufacturers through unnecessary red tape to get a licence to manufacture and export each patented drug, and even then allows for export only in a pre-negotiated quantity to a single country for at most two years. What is needed is for Canada to streamline the legal process so that developing countries and generic manufacturers can and will use it.

- ***The alternative: a simple, streamlined process for compulsory licensing***

Generic manufacturers should be able to obtain easily, at the outset, a compulsory licence to manufacture and export any patented medicine — not just those on the limited list attached to the current Regime. Generic manufacturers should be able to obtain such authorization without any particular country or specific quantity of the product predetermined.

Such legal authorization could be done via a standing statutory “compulsory licence” — that is, a specific section of the *Patent Act* could be enacted that statutorily authorizes the generic production of any patented pharmaceutical product solely for purposes of export to any eligible country specified in the legislation.

Alternatively, if the legislation were to require a specific application for a compulsory licence on a particular product, instead of requiring a generic manufacturer to apply for a separate licence to satisfy every separate order of a drug, the law could grant that manufacturer an initial compulsory licence on a drug as of right. The licence would authorize the manufacturer to export that drug to any eligible country specified in the legislation.

In either case, whether granted by statutory provision or in the form of a specific licence, certain standard conditions of the authorization, such as the obligation to pay royalties to the patent owner(s) according to the formula found in the current legislation, would be mandated by statute.

With such an authorization in hand, a generic manufacturer would be able to negotiate multiple purchasing contracts with multiple developing countries — 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. The economies of scale that could be achieved could be considerable, contributing to the goal of encouraging generic manufacturers to participate, and to lowering further the ultimate price developing countries could negotiate with the generic manufacturer.

Since the authorization would already have been obtained at the outset of the process, there would be no need for a negotiation period between generic and brand-name manufacturers over the terms of a voluntary licence (as is currently the case). A generic producers would still be required to pay royalties to the patentee(s) based on the contracts the generic producer negotiates with developing-country purchasers; by law, the generic producer would be required to disclose basic details about the value of those contracts and pay the applicable royalties to the patentee(s) on a regular basis. The existing law already contains a sensible formula that calculates the royalty payable on

any given contract based on the UN Human Development Index ranking of the country to which the product is being exported.

By granting, as the first step in the process, a legal authorization that is not specific to any one country, and by legally requiring the generic manufacturer to pay royalties in accordance with the legislation's clearly defined formula (based on whatever contracts may end up being negotiated), there would be no obligation for an interested developing-country purchaser to first step forward and risk retaliation — for example, from the United States or another country opposed to the use of compulsory licensing — all for the uncertain reward of purchasing one medicine in a predetermined quantity for a limited period of time (even assuming the generic manufacturer ultimately succeeds in obtaining the requisite licence under the Regime's rules).

In addition, countries would not be faced with the unrealistic task of guessing the quantity of the drug that will be needed in a given time period. Instead, adjustments in the quantity produced and purchased could be made to meet fluctuating needs without having to undertake the entire cumbersome process anew, . Such a streamlined, straightforward process would give generic manufacturers and developing countries much more incentive to make use of the Regime to get medicines to patients in developing countries who need them.

- ***This better alternative complies with Canada's obligations under WTO/TRIPS***

Would such an alternative mechanism be permissible under WTO rules? Clearly, it departs in some important ways from the WTO Decision that is the basis for the current Regime and that, unfortunately, has proved to be flawed. But the WTO Decision is not the only option open to WTO members. The WTO Decision states expressly:

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.⁷

Therefore, it is time to look at other “flexibilities” that are open to Canada under TRIPS. In particular, TRIPS Article 30 provides a basis for solving the problem – and indeed, this is an option that has been suggested previously by some developing countries and by the World Health Organization as one that could be used to enable easy use of compulsory licensing by developing countries needing to import lower-cost generics to address their public health problems. TRIPS Article 30 states:

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.

⁷ WTO Decision, *supra* note 3 at para. 9.

As is evident, this 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, such as the streamlined compulsory-licensing mechanism outlined here.

Recall that 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.” Furthermore, TRIPS Article 8 states that WTO “Members may, in formulating their laws and regulations, adopt measures necessary to protect public health . . . and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” TRIPS Article 30 is such a provision.

Can and should TRIPS Article 30 be interpreted and implemented so as to enact the simplified compulsory licensing mechanism proposed here? In the 2001 Doha Declaration, 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) (paras. 1–2). They also unanimously agreed that TRIPS “. . . 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” (para. 4). Clearly, WTO members 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.

In the Doha Declaration, WTO members further reaffirmed that flexibilities under TRIPS that can and should be used 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” (para 5b). In both the Doha Declaration and the subsequent WTO Decision, WTO members have expressly indicated 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.

Therefore, enacting a mechanism such as the simplified compulsory licensing mechanism proposed here cannot be considered to “unreasonably conflict with a normal exploitation of the patent” or to “unreasonably prejudice the legitimate interests of the patent owner”, and must fall within the bounds of TRIPS Article 30. It creates an exception to exclusive patent rights in Canada solely for the limited purpose of exporting lower-cost generic medicines to developing countries in need, a need recognized by WTO members. 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.

- **Canada's right and obligation to enact a better mechanism for exporting generics**

Canada has implemented the mechanism embodied in the WTO Decision. So far, Canada's model has not worked — 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 acknowledging that the WTO Decision does not address the needs of developing countries, and to implement a better model, within the bounds of WTO rules, that stands a greater likelihood of actually engaging generic producers and developing-country purchasers in increasing access to more affordable treatment for millions of people.

Canada has the clear legal right and ethical duty to use the flexibility that it retains under TRIPS Article 30 to legislate, as a set of "limited exceptions" to exclusive patent rights, the simpler, streamlined mechanism for compulsory licensing for export described above. Similarly, Canada also 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 as part of achieving fully the human right of every person to the highest attainable standard of health.⁸

Recommendation: Provide authorizations to export that are not limited to a single drug-order for a single country.

This can be done by creating a standing statutory authorization in the *Patent Act* authorizing the manufacture of generic versions of any drug patented in Canada for export to any eligible country specified in the legislation.

Alternatively, a manufacturer could be granted a single, open-ended licence on a given drug that authorizes the exportation of that drug to any eligible country specified in the legislation.

With either mechanism,

- **the authorization would not be limited to exporting a predetermined quantity of the product to a single country, and would not require a new application process for every single (tentative) contract negotiated between a generic manufacturer and a potential purchaser;**
- **the authorization should extend to permit the use of *any* patented invention necessary for the manufacture and export of the medicine in question; and**
- **the generic manufacturer would be required to remit periodically to the patentee(s) the royalties payable, which can be determined according to the existing formula in the Regime.**

⁸ E.g., *International Covenant on Economic, Social and Cultural Rights*, 993 U.N.T.S. 3, Articles 2 & 12(c).

Proposed amendments to replace current compulsory licensing process

OPTION 1: Standing statutory authorization

- *Delete ss. 21.04 and 21.05 in their entirety, and replace them with the following:*

Statutory authorization for export

21.04 Subject to sections 21.01 to 21.19 and to any prescribed conditions or requirements, any person is authorized to make, construct and use a patented invention solely for purposes of manufacturing a pharmaceutical product and selling it for export to a country or WTO Member listed in the Schedule that forms part of this Act.

Form and content of authorization

21.05 (1) The authorization must be in the prescribed form and contain the prescribed information.

Note: The holder of the authorization would still be required, by s. 21.08, to pay royalties as prescribed by the existing regulations under the Patent Act, and by s. 21.16 to disclose value of contracts for purpose of calculating royalties payable.

OPTION 2: Single licence required

- *Maintain the requirement for an application to the Commissioner of Patents for a compulsory licence, but issue a single licence that authorizes exports of the product (or products) named in the licence to any eligible developing country as listed in the Schedule, without restricting export to a predetermined quantity. This would be accomplished by amending sections 21.04 and 21.05 as follows:*

Authorization

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use any patented invention solely for purposes of manufacturing directly related to the manufacture of the pharmaceutical product or products named in the application and to selling the product or products ~~it~~ for export to a country or WTO Member that is listed in the Schedule attached to this Act any of Schedules 2 to 4 and that is named in the application.

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;

(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 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.~~

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.~~

2004, c. 23, s. 1.

Note: The holder of the authorization would still be required, by s. 21.08, to pay royalties as prescribed by the existing regulations under the Patent Act, and by s. 21.16 to disclose value of contracts for purpose of calculating royalties payable.

(b) Simplifying compulsory licensing if current process maintained

We have recommended, above, some changes to the existing Regime that would put in its place a more direct, simple and streamlined approach for granting the legal authorization to produce generic versions of patented pharmaceutical products for export to eligible countries, without predetermined quantities destined for specific countries.

We have submitted that such a revised process would be in accordance with Canada's obligations as a WTO member, as it would make use of flexibilities under TRIPS Article 30 that the WTO Decision and other WTO legal instruments clearly state are open to Canada to interpret and implement as it sees fit in its domestic legal system. Such a mechanism would enact the "rapid response" that WTO members recognized, in the preamble to the WTO Decision, is needed—but which, unfortunately, did not result from that Decision. It would eliminate what may prove to be months of negotiating with the patent-holder over the terms of a voluntary licence, remove the requirement to base the request for any particular licence on the terms of a tentative contract with a single country for a set quantity of a medicine, and introduce the flexibility needed by both developing-country purchasers and generic manufacturers.

i. Clearly delimit negotiation for a possible voluntary licence

If such a mechanism were enacted, the concerns about the current features in the Regime regarding the process of seeking a compulsory licence would be moot.

However, to the extent that the Regime continues to be modelled on the WTO Decision and the underlying provisions of TRIPS Article 31, it is imperative to more clearly define and limit the requirement, pursuant to Article 31(b), that efforts first be made to negotiate a voluntary licence with the patentee before a compulsory licence may be issued. These negotiations involve high costs and considerable delays, and create a disincentive for use of the system, which should be minimized to the greatest extent possible.

Canada's legislation should provide clear limits on the negotiations required. Currently, a minimum 30-day period is specified; there is no need, however, for such a lengthy period of time, given the parameters and limits already imposed by statute on the use of the system, including the formula specifying what a reasonable royalty rate would be in the event a compulsory licence is issued. Patent-holders should not need such an extended period of time to decide whether to agree to the request for a voluntary licence. As we have recommended previously, a period of 15 days should be more than sufficient.

Recommendation: The time for negotiating a voluntary licence from the patentee(s) should be capped at no more than 15 days.

ii. ***Eliminate requirement to disclose importing country before licence is issued***

We note here a particular example of how the legislation creating the Regime could be amended to reflect the political and economic realities faced by developing countries that might seek to use such a regime to import lower-cost medicines to address public health problems.

Under s. 21.04 of the *Patent Act* as it currently stands, the Commissioner of Patents may not issue a compulsory licence unless the applicant has provided to the patentee(s), for a period of at least 30 days, not only the name and quantity of the pharmaceutical product to be exported but also “the name of the country or WTO Member to which the pharmaceutical product is to be exported”.

As a result, for at least a month, before there is even any assurance for the would-be purchasing country that the Canadian generic supplier is able legally to supply the product for which a tentative agreement has been reached, the importing country is exposed to almost certain pressure, from the patented pharmaceutical industry and powerful countries such as the United States or other like-minded WTO members, to refrain from proceeding with the use of compulsory licensing to secure needed medicines. Recent history provides numerous examples of such pressure, extending even to threats of serious trade sanctions and other retaliation, notwithstanding that such conduct runs counter to the letter and spirit not only of agreements reached at the WTO (such as the WTO Decision that underlies the Regime) but also those states’ obligations under international human rights law to not impede access to medicines.

This is one factor that has almost certainly contributed to the fact that no country has yet notified the WTO of its intention to use the WTO Decision, whether to import Canadian-made generics under the Regime or from other jurisdictions that have implemented similar regimes. It is a further argument for replacing the current case-by-case, country-by-country process with the alternative approach proposed above, based on TRIPS Article 30, which would provide the necessary legal authorization to Canadian generic manufactures without restricting them to a particular contract for a specific quantity of a particular product to a specific, named country.

At the very least, this section of the *Patent Act* can be revised such that, even if the existing cumbersome process of applying for a compulsory licence for every specific drug order is maintained, there would be no requirement to disclose the name of the purchasing country as a precondition of obtaining the compulsory licence. Instead, it could be simply required that the generic manufacturer request a voluntary licence from the patentee(s) on the reasonable condition that the generic manufacturer will disclose the name of the purchasing country following receipt of the licence and will pay the applicable royalty rate pursuant to the existing Regime formula.

Recommendation: The *Patent Act* should be amended so as to not require advance disclosure, before a licence is obtained, of the name of the country to which the product will be exported. Instead, it should simply be required, as a condition of the licence, whether issued voluntarily or compulsorily, that the generic manufacture will pay the applicable royalty as determined by the existing Regime formula.

iii. ***Fully reflect flexibility in existing WTO rules: waive requirement to seek a voluntary licence in cases of emergencies, public non-commercial use, and when remedying patentee’s anti-competitive practice***

Finally, under TRIPS Article 31(b), the requirement of first attempting to negotiate a voluntary licence may be waived in circumstances of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use of the product in question. Canada’s legislation does not currently reflect this, although a number of other jurisdictions have done so in their implementation of the WTO Decision.

In addition, TRIPS Article 31(k) also provides that this requirement of prior negotiation may also be waived in cases where compulsory licensing is undertaken “to remedy a practice determined after judicial or administrative process to be anti-competitive”.

Following WTO rules, where the importing country wants to import the drug to address a national emergency or similar circumstance, or for public non-commercial use, or to remedy anti-competitive practices by patentee(s) in the importing country, there should be no requirement that the generic manufacturer first try to negotiate a voluntary licence before obtaining a compulsory licence.

Recommendation: The *Patent Act* should be amended so as to state explicitly that the requirement to first seek a voluntary licence from the patentee(s) does not apply:

- in the event that the importing country is facing a national emergency or other circumstances of extreme urgency;
- is importing the product for public non-commercial use; or
- has authorized the import under compulsory licence as a remedy for practices by the patentee(s) that have been determined by judicial or administrative process in the importing country to be anti-competitive.

Proposed amendments to simplify current compulsory licensing process

(should the requirement to first seek a voluntary licence for a specific product from the patentee(s) remain in the Regime)

Authorization

21.04 [...]

Contents of application

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

[...]

~~(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 [...]~~

Conditions for granting of authorization

(3) The Commissioner shall authorize the use of the patented invention only if

[...]

(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least ~~thirty~~ fifteen 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 a country or WTO Member named in the Schedule application on reasonable terms and conditions~~ the condition that the applicant agrees to pay to the patentee or patentees, as the case may be, the prescribed royalties 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 [...]~~

- *Add the following new s. 21.04(4):*

(4) The requirements in subsection 21.04(3)(c) are waived if the applicant submits, with the application to the Commissioner, documentation that satisfies the Commissioner that

(a) the country or WTO Member to which the product is to be exported has determined it needs the product to address a national emergency or other circumstance of extreme urgency;

(b) the product is for public non-commercial use in the country or WTO Member to which it is to be exported; or

(c) the country or WTO Member to which the product is to be exported has authorized use of the product without the consent of the patentee or patentees, as the case may, to remedy a practice determining after judicial or administrative process to be anti-competitive.

(c) Eligible importers

i. *Make it easier for NGOs to purchase Canadian-made generics*

Under Canada's current law — *Patent Act*, s. 21.04(2)(f) — a non-governmental organization (NGO) providing humanitarian relief (e.g., MSF) or an international agency procuring medicines for use in developing countries (e.g., UNICEF, Pan American

Health Organization, International Dispensary Association) has to get the permission of a country's government to import medicines into that country if it purchases from generic manufacturers from Canada. (This is a requirement on top of the importing country's requirement that the medicine be approved for use by its drug regulatory authority.) Requiring this extra permission for NGOs to do their work is not required by any WTO rule, and creates an additional, unnecessary barrier to patients getting the medicines they need. As long as the medicine satisfies the conditions established by the drug regulatory authority in the importing country, there is no reason why a non-governmental purchaser of Canadian-made generics importing those products into an eligible country should require the permission of the importing country's government in order to purchase its supplies from this source. This additional hurdle is easily eliminated and should be.

Recommendation: Canada should eliminate the requirement that NGOs get the permission of the importing country government, by deleting the relevant portions from s. 21.04(2)(f) of the *Patent Act*.

Proposed amendments

Authorization

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.

Contents of application

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

(f) the name of the governmental person or entity, or ~~the person or entity permitted by the government of the importing country~~ other person or entity legally entitled to import and distribute the product in the country or WTO Member, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; [...]

ii. *Treat non-WTO developing countries fairly*

Under the current legislation — specifically *Patent Act* s. 21.03(1)(d)(ii) — a developing country that is neither a WTO member nor a “least-developed country” (LDC) can procure cheaper medicines from Canadian generic producers only if:

- it is eligible for “official development assistance” according to the Organization for Economic Co-operation and Development (OECD);
- it declares a “national emergency or other circumstances of extreme urgency”; and

- it specifies the name and quantity of a specific product needed for dealing with that emergency.

These requirements create an indefensible double standard between developing countries that belong to the WTO and those that do not.

During the negotiations that ultimately led to the WTO Decision, efforts to limit sovereign developing countries to using compulsory licensing to import medicines only in “emergency” situations were rejected, and in the end the decision contains no such restriction (except in the case of middle-income and transitional countries that themselves agreed to limit their use of the system as importers in this way). It should also be remembered that in the Doha Declaration, on which the WTO Decision is based, WTO members explicitly reaffirmed that countries are free to determine for themselves the grounds upon which to use compulsory licensing (para. 5b).

Furthermore, *Patent Act* s. 21.03(1)(d)(ii) also states that a precondition to being eligible is that the importing country agrees the imported product “will not be used for commercial purposes”. This condition is not required by the language of the WTO General Council Chairperson’s Statement made in conjunction with the adoption of the WTO Decision — namely, the “shared understanding” of WTO members that the system set out in the WTO decision “should be used in good faith to protect public health and . . . not be an instrument to pursue industrial or commercial policy objectives”.⁹ But under Canada’s regime — specifically, *Patent Act*, s. 21.03(3)(d) — an importing country may be struck off the list of those eligible to import from a Canadian generic supplier if it permits such use. However, the term “commercial purposes” is undefined in Canada’s legislation. As has been noted previously:

This provision is clearly aimed at limiting the possibility of commercial competition in the importing country’s marketplace, hindering the longer-term benefit that competition could have in reducing medicine prices. It also raises questions about the distribution of imported generics via the private sector (e.g., pharmacists) in the importing country. Will this be considered a “commercial purpose”? If so, such a provision fails to recognize the reality that many people in developing countries, as elsewhere, need to turn to private pharmacies when purchasing medicines, which are also frequently paid for out of their own pocket rather than covered by a public scheme. This provision is unnecessary under TRIPS and the WTO Decision; it should not have been included in the Canadian legislation, nor should this approach be replicated by other jurisdictions.¹⁰

⁹ General Council Chairperson’s Statement of 30 August 2003, in WTO General Council, *Minutes of Meeting* (held on 25, 26 and 30 August 2003), WTO Doc. WT/GC/M/82 at 6 (para. 29), on-line: WTO <http://docs-online.wto.org>, also www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm [Chairperson’s Statement].

¹⁰ R. Elliott, “Pledges and pitfalls: Canada’s legislation on compulsory licensing of pharmaceuticals for export” (2006) 1 *International Journal of Intellectual Property Management* 94-112 at 105-106, on-line via: www.aidslaw.ca/qtag.

These additional hurdles are not required of WTO member countries under WTO rules; it is an indefensible double standard to require them of non-WTO developing countries. Patients' access to more affordable medicines should not depend on whether their country belongs to the WTO.

Finally, we note that in the event that a (non-LDC) non-WTO developing country is found to be eligible to import Canadian-made generics under the Regime, currently the legislation requires that the country be added to Schedule 4 of the *Patent Act*. This is inappropriate. Schedule 4 is the list of higher-income WTO members that have already stated they will not use the mechanism set out in the WTO Decision as importers except in cases of national emergency or other circumstances of extreme urgency. Schedule 3 is the list of developing countries that are WTO members; in the interests of equivalence and fairness, this is the list to which non-WTO developing countries should be added.

Recommendations

- 1. Eliminate the provisions in the current law that require a non-LDC, non-WTO developing country to declare a national emergency or similar circumstance, and to specify in advance the name and quantity of a particular drug, in order to become an eligible importer of generic pharmaceuticals produced under compulsory licence in Canada.**
- 2. Eliminate the requirement to promise that the imported product will not be used for “commercial purposes”, as this may unnecessarily limit distribution of the product within the importing country through private channels.**
- 3. Repeal the corresponding provisions that enable a country to be struck off the list of eligible importing countries for not satisfying these conditions.**
- 4. Treat non-WTO developing countries equally with developing countries that do belong to the WTO.**

Proposed amendments regarding treatment of non-WTO countries

Amending Schedules of countries or WTO Members to which export is authorized

21.03 (1) The Governor in Council may, by order, amend the Schedule of countries or WTO Members to which export is permitted under an authorization issued under this Act by adding the name of any country recognized by the United Nations as being a least-developed country and by adding the name of any country that is named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance.

[...]

~~(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 any country or WTO Member if the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or has ceased to be 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.~~

iii. **Regional trade groups**

Under the WTO Decision, in the case that a developing-country or LDC WTO member is party to a regional trade agreement (RTA) with other countries, at least half of whom are LDCs, it is permitted for that country, having imported pharmaceutical products under a compulsory licence, to re-export those products to the other developing-country or LDC members of that regional trade group.

At the moment, there is uncertainty under Canada's current legislative regime as to whether the Regime would permit export from Canada, under compulsory licence, of generic pharmaceutical products to an eligible country from which re-exportation to other countries in an eligible regional trade group would or might occur, in accordance with the WTO Decision.

In particular, *Patent Act* s. 21.14(g) could be interpreted as permitting the termination of the generic manufacturer's authorization in such a circumstance, on the basis that "the product was exported, other than in the normal course of transit, to a country or WTO Member other than the country or WTO Member named in the authorization."

In addition, there may be uncertainty, under the current provisions of the Regime, as to the applicable royalty rate in such a circumstance. In cases where it is known in advance that such re-exportation is planned, as part of a regional pooling between different purchasing countries in that regional trade group, such uncertainties could be resolved satisfactorily through the good faith of the patentee(s) and the licence-holder, or by specifying a particular condition in the compulsory licence itself. However, this may not be a realistic expectation.

Recommendation: The Regime should be amended to enable, without confusion, the use of compulsory licensing to supply, under a simple process and with a single licence, a number of developing countries within a regional trade group as contemplated by the WTO Decision.

Proposed amendments

This concern is largely addressed by the amendments we propose to both (a) the schedule listing eligible importing countries, and (b) the process for issuing a compulsory licence to a generic manufacturer in Canada. Under our proposed amendments, a generic manufacturer is able to obtain, at the outset, a compulsory licence that permits export of a product, without restriction to a predetermined quantity, to any country on the schedule (rather than being limited to export to one single country per licence, as is currently the case), with the condition of paying royalties based on actual contracts subsequently negotiated, according to the Regime's existing formula. The schedule of eligible countries lists all least-developed countries (as determined by the UN) and all developing countries (as listed on the OECD's list of countries eligible for development assistance).

However, in order to permit a country that is a member of a qualifying regional trade agreement to re-export to other countries that are also parties to that agreement, one additional amendment is

required to the provision in the Patent Act that currently provides for termination of a licence by the Federal Court. Therefore, to make explicit that such regional re-exportation is permitted, two sub-sections of s. 21.14 should be amended as follows:

Termination by Federal Court

21.14 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

[...]

(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 to a country 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 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 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 countries ~~the country or WTO Member named in the authorization;~~

(d) Eligible pharmaceutical products

i. List of eligible drugs in Schedule 1

As noted above, in the lengthy and divisive negotiations that ultimately led to the WTO Decision, several high-income members pushed for various restrictions on the scope of any mechanism facilitating compulsory licensing for export — including attempts to limit it to only specific pharmaceutical products.¹¹ These efforts were roundly condemned by civil society activists as unethical and unsound health policy, and firmly rejected by developing countries. Ultimately, all WTO members agreed that there would be no such limitations. As noted above, the WTO decision states simply that the mechanism in the decision applies in the case of a “pharmaceutical product”, which is defined as follows:

¹¹ F.M. Abbott, “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *American Journal of International Law* 317– 358 (providing a detailed analysis of the negotiations leading to the Decision).

“[P]harmaceutical 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.

The list of products subject to compulsory licensing, set out in Schedule 1 to Canada’s *Patent Act*, represents a step back from the international consensus achieved with the WTO Decision. By introducing a limited list of products in its implementing legislation, Canada, which had repeatedly indicated it would wait for a multilateral solution to be agreed at the WTO, has unilaterally undermined that consensus.

Furthermore, the legislation creates an unnecessarily complicated bureaucratic process for expanding the list — a federal Cabinet decision following a recommendation from each of the ministers of Health and Industry. As we asked in 2004, before the House of Commons Standing Committee on Industry, Science and Technology during hearings into the legislation creating the Regime, why is Canada’s Cabinet the gatekeeper for developing countries’ access to less-costly medicines through the use of policy tools such as compulsory licensing?¹²

In previous discussions, government officials have suggested that Schedule 1 is necessary to avoid delays due to litigation. Yet this seems misguided. As long as the definition of “pharmaceutical product” is clear, there would be little basis on which a patentee could challenge the issuing of an authorization to a generic manufacturer to make such a product for export. In fact, the experience to date with Schedule 1 has been that it creates an added hurdle to the use of the Regime, rather than easing its use and avoiding delay. We have previously expressed the concern that the process envisioned for adding products to Schedule 1 would create further delay, as well as multiple opportunities for patent-holding pharmaceutical companies to lobby successfully to block any addition.

This concern has already been shown to be well founded. During third and final reading of the legislation creating the Regime in the House of Commons in 2004, lobbying from the brand-name pharmaceutical sector led to the defeat of a motion to add two drugs to the Schedule, notwithstanding an earlier agreement by all parties at the Standing Committee (and the concurrence of Health Canada) to add these two products. And while Schedule 1 has been amended twice in response to requests from generic manufacturers and NGOs,¹³ in each case, what had been repeatedly represented as being a simple process in fact took months before the government acted, and only following repeated urging by NGOs and manufacturers. Judging from the experience

¹² Canadian HIV/AIDS Legal Network, “Global Access to Medicines: Will Canada Meet the Challenge?”, Submission to the House of Commons Standing Committee on Industry, Science and Technology, 26 February 2004, on-line via www.aidslaw.ca/gtag > Publications.

¹³ *Order Amending Schedule 1 to the Patent Act*, S.O.R./2005-267, on-line: <http://canadagazette.gc.ca/partII/2005/20050921/html/sor276-e.html>; *Order Amending Schedule 1 to the Patent Act (Oseltamivir Phosphate)*, S.O.R./2006-204, on-line: <http://canadagazette.gc.ca/partII/2006/20061004/html/sor204-e.html>.

with the Canadian legislation, any such mechanism for limiting the scope of compulsory licensing legislation to specific pharmaceutical products — which is not only unnecessary under the WTO Decision, but also contrary to its very spirit — should be avoided. Indeed, as noted by the Government in its recent consultation paper, few other countries that have implemented the WTO Decision have undermined their own legislation by including such a limited list.¹⁴

Recommendation: Schedule 1 should be deleted in its entirety. As an alternative, a simple amendment would be to add to the existing Schedule 1 the entry “any other patented product of the pharmaceutical sector.” The definitions of “pharmaceutical product” and “patented product” in the *Patent Act*, for the purposes of the Regime, need to be worded as clearly and inclusively as possible, so as to avoid any misinterpretation that would provide a basis for litigation by a patentee seeking to block use of the regime to produce a pharmaceutical product for export under compulsory licence.

ii. *Active pharmaceutical ingredients, vaccines and other technologies*

In support of achieving its stated humanitarian objective, the Regime should facilitate the export of active pharmaceutical ingredients (APIs), as well as products such as existing and future vaccines — products obviously important in addressing public health problems. Similarly, other patented technologies may be necessary to use medicines effectively (e.g., various testing technologies needed to confirm HIV infection or to monitor the effects of treatment with antiretroviral or other medicines). The WTO Decision defines “pharmaceutical product” as meaning “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems” of developing countries, expressly including “active ingredients necessary for its manufacture and diagnostic kits needed for its use” (para. 1(a)). Several other countries that have implemented the WTO Decision make it explicit that such products are covered by their regimes.

If interpreted correctly, the relevant definitions currently found in the *Patent Act* (s. 21.02) mean that the Regime does extend to include APIs, vaccines and other products such as test kits. However, to avoid any confusion, it would be advisable for the legislation to make clear that these products are covered under the definition of “pharmaceutical product.”

Recommendation: Enact amendments explicitly clarifying that active pharmaceutical ingredients, vaccines, and other patented products (e.g., test kits) are included within the definition of “pharmaceutical products” that are eligible for compulsory licensing for export under the Regime.

¹⁴ See list in note 5 *supra*. Oddly, and at odds with the much more open-ended wording of the 2003 WTO Decision, China limits eligible products to pharmaceutical products needed to treat an “infectious disease”, which term is defined to mean “HIV/AIDS, tuberculosis, malaria or other infectious diseases as listed in the document ‘PRC Measures in Prevention and Treatment of Infectious Diseases’ that have led to public health problems”: see China’s SIPO Order #27, *supra* note 5, at Article 2.

Proposed amendments regarding restricted list of products

OPTION 1: Eliminate Schedule 1

- Delete current Schedule 1.
- Delete all references in other sections to Schedule 1 — e.g., delete s. 21.03(1)(a).
- Amend the definition of “pharmaceutical product” as follows:

Definitions

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

[...]

“pharmaceutical product”
« produit pharmaceutique »

“pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector, and includes active pharmaceutical ingredients used in the manufacture of a finished product, vaccines, and any other product, such as diagnostic or monitoring products, needed for the use of a pharmaceutical 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.

* * * * *

OPTION 2: Expand existing Schedule 1

- Add to Schedule 1 the following entry:

“any other patented product, or product manufactured through a patented process, of the pharmaceutical sector, including active pharmaceutical ingredients used in the manufacture of a finished product, vaccines, and any other product, such as diagnostic or monitoring products, needed for the use of a pharmaceutical product.”

(e) Regulatory review of products for export

Requiring Health Canada approval of a generic manufacturer’s product before granting a compulsory licence for export is an additional requirement under the Regime — specifically, *Food and Drugs Act* s. 37(2) — that is not mandated by the WTO Decision. We note that no other drugs manufactured in Canada require Health Canada approval for export; 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.

Since many developing countries will require pre-qualification by the World Health Organization (WHO) of the generic product in question before purchasing it,¹⁵ requiring Health Canada approval of the generic manufacturer's product as an absolute precondition before the manufacturer can get a licence to manufacture for export can lead to duplication of effort and add unnecessary delay.

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. The Regime should be amended to reflect this variety of processes that can be relied upon by the importing country to assess the safety, efficacy and quality of products being imported, while preserving the capacity of Health Canada to provide this review if called upon, as part of assisting developing countries in obtaining lower-cost medicines of reliable quality.

Recommendation: For purposes of granting a compulsory licence authorizing production for export, Canada should at least accept either Health Canada approval or WHO pre-qualification of the product as sufficient. Alternatively, the Regime could be reformed further to accept approval by a drug regulatory authority equally stringent to Health Canada, or the importing country's own drug regulatory authority, or by a regulatory authority satisfactory to the importing country, as sufficient for granting a compulsory licence. Health Canada should continue to make available its capacity to review products for export under the Regime, on a fast-track basis, for those instances where the generic manufacturer requests Health Canada review, as this may, in some circumstances, be satisfactory to the importing country or support a faster review by the WHO Prequalification Programme.

Proposed amendments regarding regulatory review

- *Delete the current ss. 37(2) of the Food and Drugs Act and replace it with the subsections shown below:*

Exception – General Council Decision

~~(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~~

¹⁵ For information about WHO's Prequalification Programme, see: <http://mednet3.who.int/prequal/>.

~~provide otherwise.~~

Technical support for exports of pharmaceutical products manufactured under compulsory licence

(2) Despite subsection (1), a person may not export a product manufactured under an authorization obtained under this Act until such time the person has been notified in writing that the Minister [of Health] is satisfied that it meets the requirement set out in subsection (3).

(3) Before a product may be exported, the manufacturer must obtain, in writing, at least one of the following:

- (i) confirmation from the Minister [of Health] that the drug or device meets the requirements of this Act and the regulations applicable to the drug or device as though it were a drug or device to be manufactured or sold for consumption in Canada;
- (ii) approval of the product by a drug regulatory authority deemed equally stringent by the Minister;
- (iii) approval of the product by the Prequalification Programme of the World Health Organization; or
- (iv) confirmation from the head of the drug regulatory authority of the country to which the product is to be exported that the product meets that country's regulatory requirements for permitting the sale and consumption of the product in that country.

(4) Upon request by a person who has filed or intends to file an application under the relevant provisions of the *Patent Act* for an authorization to make, construct and use a patented invention solely for purposes related to the manufacture of the pharmaceutical product named in the application for export to a country or WTO Member eligible under said act, the Department shall determine whether the product meets the requirements of the Act and regulations as though the drug or device were a drug or device to be sold for consumption in Canada.

- *Amendments to s. 21.13 regarding termination of a compulsory licence are also needed to reflect the broader range of regulatory review options that may be accepted to permit export of a generic product manufactured under compulsory licence, as follows:*

Termination

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

[...]

(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, [...]

(f) Duration of the licence

There should be no arbitrary limit on the term of a compulsory licence, limiting the economies of scale needed to make compulsory licensing viable for generic manufacturers and throwing into question for potential developing-country purchasers the long-term sustainability of supplies.

The current time-limit of two years is arbitrary and not required by the WTO Decision. This measure constitutes a major barrier to the participation of generic companies, since they must re-initiate the long approval process to continue exporting the product beyond a two-year period. This also prevents generic companies from guaranteeing to purchasers that they will be able to continue supplying after two years. The current two-year limit should be abolished, and a compulsory licence should run for the remainder of the patent term on the originator product.

It has been suggested previously that such a limit is needed to preserve flexibility for developing countries. However, this rationale is untenable:

Such a paternalistic approach, trying to legislate by proxy a limit on the term of a contract, seems strange given the government's general unwillingness to interfere with parties' freedom to bargain in the marketplace. There is little reason to believe that developing countries (or other bulk purchasers of pharmaceuticals) are unable to adequately assess and project their own medicine needs and contract accordingly. Furthermore, such a proposition is irrelevant to the issue of compulsory licensing; should this argument not also be applicable in every situation where a developing country is purchasing medicines from a pharmaceutical supplier, be it a brand-name company or a generic one? The fact that a generic producer may, in respect of a specific drug that is still patented in Canada, need a compulsory licence to manufacture and supply that medicine is a secondary consideration. It seems, rather, that this cap represents a misguided and unnecessary attempt to constrain generic producers' ability to compete effectively in the marketplace, by limiting the term of a compulsory licence available under the legislation.¹⁶

As a much less satisfactory alternative, if there is a specified term of a licence, extending or renewing the licence should be a simple, largely automatic process. There should be no need to undertake anew the entire process (including attempting to negotiate a voluntary licence with the patentee) simply to continue a relationship with a developing-country purchaser beyond the term of the original contract, or to expand production of the same product to supply new customers, whether in the same or another eligible importing country.

Recommendation: Section 21.09 of the *Patent Act* should be repealed, and should be replaced with a section that makes clear that, unless revoked on other grounds set out in the legislation, a

¹⁶ Elliott, *supra* note 9 at 107.

compulsory licence is valid so long as the product in question remains under patent (or patents) in Canada.

Proposed amendment

Duration

21.09 An authorization granted under ~~subsection 21.04(1)~~ this Act 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.

(g) “Good faith” clause: unnecessarily restrictions on dissemination of medicines

Under the current legislative regime (s. 21.17 of the *Patent Act*), the patentee(s) may apply to the Federal Court of Canada for an order terminating a compulsory licence, or ordering a royalty higher than what is specified by the sliding scale in the regulations under the *Patent Act*, on the basis that a generic company’s contract with a purchaser is “commercial” in nature.

In such an application, the patent owner must allege that the generic producer is charging an average price for the product that exceeds 25 percent of the average price being charged for the patented product in Canada. In determining whether the agreement is “commercial” in nature, the Federal Court must consider:

- the need for the generic manufacturer holding the compulsory licence to make “a reasonable return sufficient to sustain a continued participation in humanitarian initiatives”;
- the ordinarily levels of profitability in Canada of commercial agreements involving pharmaceutical products; and
- international trends in prices as reported by the UN for the supply of pharmaceutical products for humanitarian purposes. If the generic producer can demonstrate, through an audit supervised by the Court, that its average price is less than 15 percent above its direct manufacturing costs, the Court may not issue such an order.

It has been suggested that these provisions in the Regime seek to control the prices charged by generic producers to developing-country purchasers. Indeed, that may well be the objective, as well as the effect. However, the measures adopted in pursuit of this

objective are ill considered, assuming for the sake of argument that they are even necessary given likely competition in the global marketplace — from either brand-name companies pressured into lowering their prices or, more importantly, from other generic manufacturers, including those in other countries, some of whom likely have lower costs of production on some fronts.

The objective of constraining prices charged by generic manufacturers exporting medicines under compulsory licence from Canada could be achieved through other means, such as through conditions imposed in the compulsory licence itself when issued. Instead, the government chose a far less direct method of achieving its objective, one that places enforcement of this crude price control provision in the hands of patentees, who have not only a long history of vexatious litigation against generics aimed at delaying and undermining marketplace competition, but also an obvious incentive and now a legal basis for such tactics embedded right in the legislation itself.

It has also been suggested that these provisions to control generic manufacturers' prices reflect the humanitarian, and not commercial, spirit of the WTO Decision and give effect to Canada's obligation to act in "good faith" to prevent the use of the system agreed in that decision from being used to pursue industrial or commercial policy objectives. However, such a detailed and obvious disincentive to generic producers using the system is in no way required by the WTO Decision or the accompanying Chairperson's statement of the same date, nor by TRIPS itself. The stated commitment in the Doha Declaration, referred to again in the WTO Decision, and reaffirmed yet again in the Regime, is to facilitate access to medicines to address public health problems faced by developing countries. Yet the Regime has created further privileges and legal mechanisms for patent-owners to interfere with the simple, straightforward use of compulsory licensing to supply generic pharmaceuticals to developing countries.

Recommendation: Eliminate patent-holders' extra litigation rights by repealing the relevant elements of sections 21.08 and 21.14, and all of section 21.17 of the *Patent Act*.

Proposed amendments

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.

Termination by Federal Court

21.14 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;~~

~~(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 knowledge consent of the holder of the authorization, re-exported in a manner that is contrary to the General Council Decision to a country or WTO Member other than one that appears on the Schedule of countries and WTO members to which export is permitted under an authorization under this Act or that is a party to a regional trade agreement with other countries at least half of whom are least-developed countries;~~

~~(g) the product was exported, other than in the normal course of transit, to a country or WTO Member other than one that appears on the Schedule of countries and WTO members to which export is permitted under an authorization under this Act or that is a party to a regional trade agreement with other countries at least half of whom are least-developed countries the 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.~~

2004, c. 23, s. 1.

➤ *Delete s. 21.17 in its entirety.*

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 fabrication*»~~

~~"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.~~

4. Conclusion

When the legislation creating Canada's Access to Medicines Regime was enacted in 2004, it passed with the support of every single senator and member of Parliament, and every single party represented in Parliament declared its support for legislation that was supposed to help get more affordable medicines to patients in need in developing countries.

To date, however, the Regime has not delivered on the pledge. All parties should commit themselves to making the necessary changes to get the Regime right. We submit that the reforms recommended here would significantly increase the likelihood of fulfilling the promise.

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 21.2 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 21.03 to 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 patented product, or product manufactured through a patented process, of the pharmaceutical sector, and includes active pharmaceutical ingredients used in the manufacture of a finished product, vaccines, and any other product, such as diagnostic or monitoring products, needed for the use of a pharmaceutical 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 of countries or WTO Members to which export is authorized

21.03 (1) The Governor in Council may, by order, amend the Schedule of countries or WTO Members to which export is permitted under an authorization issued under this Act by adding the name of any country recognized by the United Nations as being a least-developed country and by adding the name of any country that is 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 1~~

~~(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 any country or WTO Member if the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or has ceased to be 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.

OPTIONS FOR REFORMING COMPULSORY LICENSING PROCESS: ss. 21.04 & 21.05

Authorization

OPTION 1: Standing statutory authorization

Statutory authorization for export

21.04 Subject to sections 21.01 to 21.19 and to any prescribed conditions or requirements, any person is authorized to make, construct and use a patented invention solely for purposes of manufacturing a pharmaceutical product and selling it for export to a country or WTO Member listed in the Schedule that forms part of this Act.

Form and content of authorization

21.05 (1) The authorization must be in the prescribed form and contain the prescribed information.

* * * * *

OPTION 2: Single licence required

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use any patented invention solely for purposes of manufacturing directly related to the manufacture of the pharmaceutical product or products named in the application and to selling the product or products it for export to a country or WTO Member that is listed in the Schedule attached to this Act, any of Schedules 2 to 4 and that is named in the application.

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;

~~(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 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.~~

2004, c. 23, s. 1.

Note: If the legislation retains a requirement to apply for a compulsory licence to authorize manufacture and export (i.e. Option 2), and contrary to the recommendation here, also retains the requirement to first seek a voluntary licence from the patentee(s), then the following amendments to subsection 21.04(3) should be made and a new subsection 21.04(4) as follows should be added to reflect fully the flexibility currently afforded under TRIPS:

Conditions for granting of authorization

(3) The Commissioner shall authorize the use of the patented invention only if [...]

(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least ~~thirty~~ fifteen 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~~ a country or WTO Member named in the Schedule application on reasonable terms and conditions ~~the condition that the applicant agrees to pay to the patentee or patentees, as the case may be, the prescribed royalties 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 [...]~~

(4) The requirements in subsection 21.04(3)(c) are waived if the applicant submits, with the application to the Commissioner, documentation that satisfies the Commissioner that

(a) the country or WTO Member to which the product is to be exported has determined it needs the product to address a national emergency or other circumstance of extreme urgency;

(b) the product is for public non-commercial use in the country or WTO Member to which it is to be exported; or

(c) the country or WTO Member to which the product is to be exported has authorized use of the product without the consent of the patentee or patentees, as the case may, to remedy a practice determining after judicial or administrative process to be anti-competitive.

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.~~

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 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 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;~~

~~(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 to a country 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 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 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 countries~~the 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.~~

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 the later of the day on which the authorization was granted and the day on which the holder of an authorization enters into an 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.

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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) 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.~~

Technical support for exports of pharmaceutical products manufactured under compulsory licence

(2) Despite subsection (1), a person may not export a product manufactured under an authorization obtained under this Act until such time the person has been notified in writing that the Minister [of Health] is satisfied that it meets the requirement set out in subsection (3).

(3) Before a product may be exported, the manufacturer must obtain, in writing, at least one of the following:

- (c) confirmation from the Minister [of Health] that the drug or device meets the requirements of this Act and the regulations applicable to the drug or device as though it were a drug or device to be manufactured or sold for consumption in Canada;
- (d) approval of the product by a drug regulatory authority deemed equally stringent by the Minister;
- (e) approval of the product by the Prequalification Programme of the World Health Organization; or
- (f) confirmation from the head of the drug regulatory authority of the country to which the product is to be exported that the product meets that country's regulatory requirements for permitting the sale and consumption of the product in that country.

(4) Upon request by a person who has filed or intends to file an application under the relevant provisions of the *Patent Act* for an authorization to make, construct and use a patented invention solely for purposes related to the manufacture of the pharmaceutical product named in the application for export to a country or WTO Member eligible under said act, the Department shall determine whether the product meets the requirements of the Act and regulations as though the drug or device were a drug or device to be sold for consumption in Canada.

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