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

Interagency Coalition on AIDS and Development | Coalition interagence sida et développement

The Jean Chrétien Pledge to Africa Act and its Impact on Improving Access to HIV/AIDS Treatment in Developing Countries

Introduction

The introduction of antiretroviral therapy (ARV) in high income countries has reduced deaths from AIDS by over 70%. Yet millions of people in the developing world still lack access to medicines they need, be it anti-retroviral drugs that fight the virus' effect on the immune system or drugs to prevent and treat opportunistic infections that can be painful and deadly. There are many reasons for the lack of access to ARVs and other medicines, but high drug prices are one significant barrier.

Prohibitive drug prices result, in part, from strict rules on intellectual property that allow drug companies holding patents on medicines to charge higher prices because of the monopoly granted by the patent. The prices of the first line of ARVs, used in combination to treat people living with HIV/AIDS, have come down significantly, thanks to competition between brand-name companies and generic producers. This competition became possible in part because pharmaceutical patents were not recognized in all countries, thus allowing for the production of lower-cost generic drugs and their export to other countries where these drugs were also not patented. However, countries that were able to produce generic medicines for export have recently had to conform to the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This has meant losing some of this flexibility. It is now more complicated to produce generic drugs, particularly newer ARVs and other increasingly essential drugs, including for export to other developing countries.

The cost of treatment remains a major concern for developing countries facing the pandemic. The different initiatives aiming at improving access to less expensive treatment are therefore watched with great interest. Canada's *Jean Chrétien Pledge to Africa Act*, brought into force in May 2005, is such an initiative. This legislation implements a 2003 WTO decision that allows countries with pharmaceutical manufacturing capacity to override patents in order to make generic drugs for export to eligible developing countries that need less expensive medicines.

This document assesses some of the measures taken recently to improve access to more affordable ARV therapy in developing countries. It provides a synopsis of the key WTO rules and developments, and of the Canadian law, the concrete benefits of which have yet to be realized.

TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a treaty of the World Trade Organization adopted in 1994 when the WTO was created. TRIPS requires all WTO member countries to adopt certain rules on intellectual property, including granting patents on pharmaceuticals. Until TRIPS, some countries, including some key developing countries with the industrial capacity to manufacture generic medicines, did not allow patents on pharmaceuticals. But under TRIPS, all WTO member countries must grant such patents, for a minimum of 20 years from the date of filing the patent application. High income countries had to ensure their laws complied with TRIPS by 1996. Developing counties and certain economies in transition had to comply by 2000, although in the specific case of pharmaceuticals they could wait until 2005 to grant patents if their law did not already provide for patents in this area. The original deadline for least developed countries (LDCs) to comply with TRIPS was originally 2006, but this has been extended to 2013 (and to 2016 in the case of patents on pharmaceuticals).

The Doha Declaration

As a general rule, it is illegal to copy any drug that is still under patent. However, at the WTO Ministerial Conference in Doha, Qatar in November 2001, WTO member countries adopted a Declaration in which they agreed that TRIPS should not prevent members from taking measures to protect the public health of their citizens. The Doha Declaration repeats the "flexibilities" contained in TRIPS that countries may use to overcome the barriers posed by patents. For example, through a practice known as "parallel importing", a country may import patented drugs from another country where the patent-holding manufacturer sells them for less.

"Compulsory licensing" is another flexibility permitted under TRIPS, and is central to current global efforts to scale up access to medicines. A compulsory licence on a patented drug authorizes a generic drug manufacturer to make a version that is therapeutically equivalent but less expensive. Under TRIPS, countries are free to decide the grounds on which compulsory licensing can be done. For example, this could be done in case of a national emergency, but contrary to misrepresentations by some governments and pharmaceutical companies, TRIPS does not limit compulsory licensing just to emergency situations. Another basis for compulsorily licensing a patented invention could be to compensate for anti-competitive practices by the company holding the patent. Compulsory licensing may also be done on purely "public interest" grounds. It is up to each country to decide whether and how it will make compulsory licensing possible under its laws.

TRIPS says that usually a generic company must first seek a voluntary licence from the company holding the patent, in exchange for some sort of remuneration (e.g., a royalty fee). However, if no agreement can be reached with the patent-holder "on reasonable commercial terms and conditions" and within a "reasonable period of time", then a compulsory licence allows the generic company to make the drug without the patent-holder's consent (although the patent-holder still must be paid "adequate remuneration"). In some cases, such as the situation where a compulsory licence is issued because of a national emergency, there is no need to try negotiating first with the patent holder for a voluntary licence.

The WTO Decision of 30 August 2003 (the "paragraph 6 decision")

By adopting the Doha Declaration in 2001, WTO Members recognized some of developing countries' concerns about access to medicines and reaffirmed that TRIPS rules should not prevent countries from making effective use of compulsory licensing to get access to lower-cost, generic products. In paragraph 6 of the Doha Declaration, they also recognized a problem under WTO rules for countries that are unable to produce generic drugs domestically and

therefore need to import them. TRIPS says that products made under compulsory licences must be "predominantly for the supply of the domestic market". This limits the quantity of generic medicines produced under a compulsory licence that can be exported from one WTO member country to any other country. Therefore, even if a developing country needing less expensive medicines decided to import generics, this rule restricts other countries from supplying them. This undermines the ability of the importing country to use compulsory licensing effectively as a tool to get lower-cost treatment for patients.

Under pressure from health activists and countries unable to manufacture generic drugs domestically, WTO Members decided on August 30, 2003 to adopt an "interim waiver" of this restriction. This means that compulsory licensing may be done in one country to produce generics for export in significant quantities to countries needing medicines to address public health problems. While theoretically introducing some further flexibility into TRIPS, this "solution" was criticized by many activists and some developing countries because it requires a complex mechanism for granting compulsory licences needed to permit exports of generics to countries in need. The system requires order-by-order, drug-by-drug and country-by-country procedures, ignoring the fact that generic pharmaceutical manufacturers have little financial incentive to produce small volumes of drugs. To be competitive, generic companies need to take advantage of economies of scale and larger bulk orders, which could mean, in some cases, supplying several countries at a time. The "solution" is therefore procedurally cumbersome and also may not reflect the reality of the pharmaceutical market. In addition, the political reality is also such that countries taking measures such as compulsory licensing face considerable pressure from powerful countries, including threats of trade retaliation. In addition, countries such as the U.S. are undermining the possible use of this mechanism agreed at the WTO by negotiating with developing countries a range of bilateral or regional trade agreements that contain even more stringent patent rules, including on medicines.

In December 2005, the WTO General Council decided that this interim waiver would be converted into a permanent amendment to TRIPS. WTO Members agreed the amendment would take effect once it is accepted by two-thirds of WTO Members, and set themselves a deadline of December 2007 for this (although this could be extended further). The interim decision from August 2003 remains in effect until the permanent TRIPS amendment comes into effect. Health activists are concerned that the supposed "solution" first agreed in August 2003 has been made permanent as a TRIPS amendment even though it has not yet been tested and shown to be effective and efficient.

Canada's implementation of the 2003 WTO decision

The Jean Chrétien Pledge to Africa Act

In October 2003, under pressure from Canadian civil society and Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa, the Canadian government committed itself to implement the WTO decision from August 2003. The *Jean Chrétien Pledge to Africa Act* (JCPA) was presented as a legislative priority of the then Prime Minister and received all-party support in Parliament. During its drafting, brand-name pharmaceutical companies, generic manufacturers and civil society organizations were consulted by the government. These groups also made submissions before a Parliamentary committee reviewing the legislation before it was enacted.

In May 2004, the Canadian Parliament set a global precedent by enacting the JCPA. The legislation's stated objective is to facilitate "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." However, it took some time before the legislation came into effect. After further pressure from civil society groups, the federal government finally proclaimed the JCPA into force on May 14, 2005 – exactly one year after it had been made law. The regulations accompanying the legislation were published on June 1, 2005. Canadian NGOs have characterized the legislation as having both some positive features and as containing several flaws that undermine its possible effectiveness.

Negative aspects of the legislation

Limited list of pharmaceutical products for which a compulsory licence can be issued

The JCPA includes a list of drugs (Schedule 1) that can be produced under compulsory licence for export, even though such a list is not required by the August 2003 WTO Decision, which simply refers to any "pharmaceutical product". Any future change to Schedule 1 requires a decision by the federal Cabinet. This limits Canada's ability to adapt as quickly as required. For example, fixed-dose combination (FDC) formulations of ARVs are critical to scaling up access to AIDS treatment, as recommended by the World Health Organization. However, any such product would need to be added to the list before a generic manufacturer could get licences to make it for export. Having a limited list creates an additional hurdle to using the legislation, delay while a request for an amendment is considered, and opportunities for pharmaceutical companies holding patents on medicines to lobby against any new drug being added to the list. During the final Parliamentary debate before passing the legislation, after being lobbied by the pharmaceutical industry, the government voted against proposals to add new medicines which all parties had already agreed to during parliamentary committee discussions. As a result, Bayer's patented pneumonia drug, moxifloxacin, was kept off the list of medicines.

Additional hurdle in supplying ARVs in fixed dose combinations (FDCs)

The JCPA requires that any generic drug produced under compulsory licence for export must go through the same review process as if it were to be approved for sale in Canada. The standard practice is to do an abbreviated review based on the data submitted by the generic manufacturer showing that their product is equivalent to a brand-name product already approved. But in the case of FDCs, combining more than one medicine into the same tablet, there are few such products already approved. Health Canada's review system will need to be flexible enough to do an effective yet rapid assessment of a generic manufacturer's FDC that is needed for scaling up treatment in developing countries.

Double standard between WTO members and non-members

The JCPA allows Canadian-made generics to be exported under compulsory licences to countries that do not belong to the WTO. But in the case of developing countries that are not WTO Members (and that are not "least-developed"), it imposes unnecessary preconditions that will likely make the legislation of little benefit. For example, the JCPA requires that such a country declare a national emergency or "circumstances of extreme urgency" in order to be even eligible to import from a Canadian generic manufacturer. Moreover, the country must agree the imported generic drugs will not "be used for commercial purposes". But this term is not defined and it arguably limits the distribution channels in the importing country to only public facilities, even though it may be necessary, for example, to operate through private pharmacists. Neither of these conditions apply to developing countries

that belong to the WTO, so there is little justification for this double-standard.

Limited length of the licence

A compulsory licence granted under Canadian legislation is limited to two years. It may be extended for an additional two years, but only for the purpose of completing the export of the quantity of the medicine that was originally approved. After two years, the generic manufacturer must apply again for a new compulsory licence if it wants to export more of the medicine, to either the same country or another purchaser. This limitation is a significant flaw of the JCPA, especially because such restriction on the term of a compulsory licence is not required by any WTO rules. Generic manufacturers are concerned that the financial costs and risks associated with obtaining the required regulatory approvals and scaling up production will be greater than the short-term revenues that could be made under any contract that is limited in this way. The option to apply for a new licence is there, but this creates additional costs and opportunities for intervention in the interim by the company holding the patent, meaning this is just an additional disincentive for generic companies considering using the legislation.

Positive Aspects of the New legislation

Setting a precedent

The JCPA is the first detailed national law to allow compulsory licensing for the purpose of exporting generic pharmaceuticals to developing countries under the August 2003 WTO Decision. The fact that a high-income, G7 country took this initiative is politically important because it helps generate momentum for using compulsory licensing to improve access to medicines. In addition, the Canadian model is one that may be useful for other countries that might be considering similar initiatives, by learning from both its positive features and avoiding its limitations.

Clearly defined, low compensation royalties

TRIPS is vague on the question of compensation to patent-holders. In the event of negotiating for a voluntary licence, it simply refers to “reasonable commercial terms and conditions”. If no agreement on a voluntary licence can be reached, and a compulsory licence is issued, it simply states that "adequate remuneration" must be paid to the patent holder. The uncertainty as to the meaning of these requirements gives substantial power to the patent holder, who can drag out the negotiating process. As well, the possibility of having to litigate in court over whether a reasonable period of time for negotiations has passed, or as to what constitutes a reasonable royalty, is a major disincentive to any generic producer that might consider manufacturing medicines for export under a system like the August 2003 WTO decision.

By contrast, the Canadian law defines "adequate remuneration" by providing a clear formula for calculating in advance the specific royalty rate payable in any given situation. That formula links the royalty payable to the ranking of the importing country on the UN's Human Development Index (HDI), which is a comparative measure of well-being in countries, based on factors such as life expectancy, literacy, and income levels. According to the formula, the maximum royalty payable for the top-ranked country is 4% of the total value of the product to be exported under a licence. The figure is considerably lower in the case of most developing countries, given their HDI ranking. This part of the Canadian law creates a degree of certainty about the royalty, which is very important to generic producers if they are contemplating using the system.

Clear negotiation period for a voluntary licence

According to TRIPS, it is only when the generic producer has not managed to obtain a voluntary licence from the patent holder "within a reasonable period of time", that the competent

authority may issue a compulsory licence. Without any clear definition of what constitutes a reasonable period of time, it is open to the company holding the patent to extend negotiations and to reject reasonable proposals for remuneration from the generic manufacturer. There is, therefore, less incentive for a generic producer to try to get a licence. Fortunately, the Canadian law is much clearer: the period of negotiations over a voluntary licence has been fixed at 30 days. This means that after that period, if no agreement has been reached, the generic company can apply for a compulsory licence, which will be issued with the specific royalty rate that is clearly defined by law.

Concrete outcomes

The efficacy of the Canadian law remains to be seen. As of this writing, not a single patient from a developing country has received generic drugs exported from Canada under this law. This should not be a surprise. Bringing the generics to market under this legislation involves many steps: determining the formulation, seeking the different ingredients, preparing the drugs, packaging and different efficacy tests (control tests on intermediate products, control tests on finished product). For generic drugs, there is no need to go through the whole clinical trial process, as these trials have already been done for the brand-name drug. But bioequivalence tests are needed; these determine if the generic drug delivers the active ingredient in a way that is therapeutically equivalent to the original product.

After this first phase, which can take months, the generic producer must get Health Canada approval for the drug. This can also take several months. Under the JCPA, the generic manufacturer must also satisfy Health Canada that its product is sufficiently distinguished (e.g., through size, shape or colour, etc. as well as markings on the tablet itself) from the brand-name drug sold by the patent holder in Canada.

It is only after these steps have been completed, and when the product is ready to go to market, that the generic company can seek a compulsory licence (assuming that the patent-holder have not agreed to a voluntary one).

In addition, before a compulsory licence can be issued under the Canadian law, the generic manufacturer must tell the patent-holding company the name of the country that will be importing the generic product, as part of the effort to first negotiate a voluntary licence. This means that countries seeking to use the Canadian compulsory licensing law to get lower-cost medicines will likely face considerable pressure right away from the patent-holding company and likely other countries, such as the U.S., to refrain from such a step.

Given the duration of the manufacturing and approval process, and the apparent lack of strong financial incentives for generic manufacturers, and some developing countries' concerns about retaliation, it is not surprising that not a single medicine has yet been exported to any developing country under the JCPA.

Generic companies: will they use the JCPA?

The success of the JCPA requires action by the private sector. Is there a market for Canadian generic medicines in the developing world? The extent to which the JCPA will lead to Canadian generic companies supplying medicines needed for people living with HIV/AIDS or other health conditions remains to be seen. However, Canadian generic companies have proven they can compete globally in at least some markets. The Canadian Generic Pharmaceutical Association (CGPA), which represents Canada's generic drug companies, reports that 40% of sales volume of its member companies comes from exporting products to 120 countries (although a significant portion of this amount seems to

come from other high-income countries). However, there may be particular niche markets or classes of drug where Canadian generic drug manufactures will be competitive.

The World Health Organization estimates that, as of June 2005, more than 1.3 people living with HIV/AIDS in sub-Saharan Africa were receiving ARV treatment, but another 6.5 million were in need. With the growing mobilization of financial resources to scale up treatment access, and the need to use those resources most cost-effectively by relying, where possible, on lower-priced generics, this is a massive potential market. The possibility of gaining a foothold in this market, particularly if economies of scale could be achieved by negotiating large, multi-year and multi-country purchases, may help motivate generic producers in Canada to consider using the JCPA to produce ARVs for export.

However, this has not yet been the case. After the passage of the JCPA, in August 2004, Canadian government officials, the medical humanitarian organization Médecins Sans Frontières Canada (MSF), and representatives from the Canadian generic pharmaceutical industry met to discuss moving ahead with using the legislation once it came into force. MSF was asked to identify drugs they would require for use in their treatment programs in various countries. At MSF's request, Apotex Inc., the largest generic manufacturer in Canada, agreed in January 2005 to produce a fixed-dose combination antiretroviral drug containing the medicines zidovudine, lamivudine and nevirapine (AZT+3TC+NVP). At the time of writing, Health Canada had indicated the product had met its regulatory requirements, but no public announcement had yet been made regarding a possible licence for Apotex to export the drug for use in one or more developing countries. If this first attempt at using the JCPA proceeds successfully, it could encourage other generic companies to use the legislation to help respond to the public health needs of developing countries.

Conclusion

In the absence of concerted efforts by generic manufacturers and the federal government, there will be little concrete benefit to report when Parliament reviews the legislation in 2007.

We call on Canada to:

- Promote in developing countries the opportunity to obtain more affordable medicines from Canadian generic manufacturers.
- Broker exploratory meetings between Canadian generic manufacturers and health ministries in developing countries.
- Remove unnecessary red tape that dissuades generic drug manufacturers and developing countries from using the legislation.

We call on the generic drug industry in Canada to:

- Seek opportunities to export generic medicines to developing countries.
- Collaborate with developing country health ministries and NGOs in identifying medicines Canadian generic manufacturers can produce.
- Make special efforts to develop fixed-dose combinations and paediatric formulations of HIV/AIDS drugs.

Additional information

Canadian Generic Pharmaceutical Association
www.canadiangenerics.ca

Canadian HIV/AIDS Legal Network
www.aidslaw.ca

Consumer Project on Technology
www.cptech.org

Intellectual Property Watch
www.ip-watch.org

Interagency Coalition on AIDS and Development (ICAD)
www.icad-cisd.com

MSF Campaign for Access to Essential Medicines
www.accessmed-msf.org

WTO "Frequently Asked Questions" brief on compulsory licensing:
www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

WTO TRIPS Agreement
www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

Funding for this publication was provided by the Public Health Agency of Canada and the International Affairs Directorate of Health Canada. ICAD and the Canadian HIV/AIDS Legal Network would like to thank Médecins sans frontières for their comments and advice during the writing of this document. The opinions expressed in this publication are those of the authors/researchers and do not necessarily reflect the official views of the Public Health Agency of Canada or Health Canada.
Ce feuillet est également disponible en français

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

Interagency Coalition on AIDS and Development | Coalition interagence sida et développement

Intellectual Property and Access to HIV/AIDS Treatment Case Studies

Recent TRIPS-related developments in the rest of the world

In developing countries

Until now, India, Brazil and Thailand have been among the biggest generic ARV producers, both for their own people and for export. This production has been crucial for the supply of affordable treatment in the developing world. It has resulted in competition between producers, which has reduced the price of many ARVs from as much as US$15,000/year per person for a course of combination treatment to as little as US$150/year per person. How have recent outcomes of WTO or bilateral agreements changed the situation?

The Indian case

Until 2005, Indian law did not recognize patents on pharmaceutical products, which enabled Indian companies to make their own generic versions of medicines. India had become one of the world's primary exporters of generic medicines, including AIDS drugs, particularly to many developing countries. As of January 1, 2005 however, the transition period to conform to TRIPS came to an end for a country such as India. In March 2005, the Indian parliament passed amendments to the Patent Act such that pharmaceutical products and processes can now be patented in India.

Some of the first-line ARVs listed on the World Health Organization's model List of Essential Medicines were already in the public domain before the advent of TRIPS in 1995, and therefore no longer patentable. This means Indian generic companies can continue to produce them legally. But this is no longer the case for drugs patented in other countries between 1995 and 2005. Most of the producers of these drugs will have filed for patents in India. As required under TRIPS, those patents have been on hold in a "mailbox" until Indian law was changed in 2005 to comply with TRIPS by recognizing pharmaceutical patents. Under TRIPS, if those patent applications are deemed valid under Indian law, the remainder of the 20 year patent term must now be granted in India to the patent holder. This means that any production of these drugs in India can only legally happen under a compulsory licence or similar authorization. Without such authorization, and hence without competition from generic producers, the price of the drugs will be the monopoly price the patent holder can charge.

Fortunately, the Indian legislation creates a system of automatic compulsory licensing for a generic producer who has made a "significant investment" and is already producing and marketing a drug in India, allowing this production to continue despite a patent. In exchange, as with any compulsory licence, the generic manufacturer must pay a "reasonable royalty" to the patent holder, although the law has not defined what amounts to a reasonably royalty. It remains to be seen what effect this will have on continued production of these generics.

But most drugs will not be covered by this automatic licensing clause – particularly many of the second-line or other new ARVs, which are nearly 10 times more expensive than first-line drugs, and will increasingly be needed as resistance to the first-line ARVs emerges. These drugs will be fully covered by patents. If Indian manufacturers are to be able to export generics of these medicines, the only solution will be to obtain compulsory licenses under the new Indian legislation. In addition to possible procedural hurdles and uncertainty under the new rules on compulsory licensing that now exist in Indian law, this will likely be made difficult by the inevitable political and commercial pressures exerted by both brand-name pharmaceutical companies and countries like the U.S.

India is but one, particularly important, example of how implementing TRIPS will likely restrict the existing sources of supply for lower-cost generic medicines that many developing and other countries need to import. Following the new Indian legislation, access to newer drugs is expected to become more difficult, as these drugs may be subject to at least 20 years of patent protection in all but the least developed countries (and the occasional non-WTO country). Even those countries that are not yet required to give pharmaceutical patent protection under TRIPS will feel the impact, if they need to import medicines from generic producers in countries, such as India, where compulsory licensing is now required in order to export in any significant quantity.

The Brazilian case

Brazil is commonly seen as one of the few countries that will be able to use the exceptions outlined in TRIPS to manufacture patented medications and export them. The Brazilian government's response to HIV is considered a model AIDS program, providing free ARV treatment currently to about 160,000 patients. Part of the reason for this success is Brazil's capacity to manufacture generic ARVs, particularly first-line drugs which were developed before Brazilian law was changed in 1996 to recognize pharmaceutical patents. However, second-line and paediatric therapies are patented and are only available at prices fixed by brand-name companies.

For example, in 2005, the ARV Kaletra® (lopinavir + ritonavir), made by U.S.-based multinational Abbott Laboratories, accounted for a third of Brazil's annual budget for ARVs. The Brazilian government requested that Abbott reduce its price to match what it would cost Brazil to produce it domestically, and also asked Abbott to engage in "technology transfer" by sharing its manufacturing process. Brazil indicated that, without such steps being taken, it would proceed to compulsory licensing of the drug, so that it could be manufactured domestically and more cheaply. Abbott eventually agreed to fix a lower price for a period of 6 years, in exchange for Brazil agreeing to forego using generics or seeking further price reductions.

This was not Brazil's first hard negotiation with multinational brand-name pharmaceutical companies. It has successfully compelled drug companies to lower prices on AIDS medicines several times in recent years by threatening to break their patents and produce generic versions locally. Still, the outcome of this particular negotiation process – i.e., agreeing to forego the use

of compulsory licensing —was disappointing, including for other developing countries, because it abandoned the immediate possibility of manufacturing a second-line generic ARV.

The Thai case

Like Brazil, Thailand has the domestic capacity to manufacture generic medicines, and is producing some ARVs through its Government Pharmaceutical Organization. But a major threat to access to medicines comes from the U.S.-Thailand Free Trade Agreement that is currently being negotiated in secret. As already achieved in a string of similar agreements with other countries and regions (Jordan in 2000, Chile in 2003, Singapore in 2003, Australia in 2004, Bahrain in 2004, five Central American countries in 2004, Morocco in 2004 and Peru in 2005), the U.S. proposals aim to block generic competition and in other ways reduce the ability of governments to control drug prices.

For example, the U.S. is proposing not only stricter limits on compulsory licensing but also extensions of pharmaceutical patent terms beyond 20 years from the date of the patent application. It is also proposing rules on "data exclusivity" would require generic drug companies to conduct their own clinical trials of the safety and efficacy of their "new" drugs, rather than being able to use data submitted by the brand-name company in getting original marketing approval for the originator product. This would create additional expense and delay, and also would unethically require repetition of unnecessary research, when all that should be required is to demonstrate the "bioequivalence" of the generic product to the originally approved brand-name drug. All of these proposals go well beyond what is currently required under TRIPS and would limit further the policy options open to Thailand to promote access to affordable medicines. Thai civil society and international NGOs have mobilized in an effort to block such an agreement that would limit Thai patients' access to lower-cost medicines. At the time of writing, these concerns have been ignored and the Thai/US negotiations are proceeding.

In high-income countries

European Union

In May 2006 , the European Parliament and the Council of the European Union adopted a regulation that provides direction toEU countries in implementing the August 2003 Decision in a uniform manner. This regulation came into force in June 2006

The EU regulation is both better and worse than the Canadian legislation.

- The EU regulation is more flexible in that it does not include a limited list of drugs subject to compulsory licensing for export, one of the flaws of Canada's law.

- Like the Canadian law, it allows export to all least-developed countries regardless of WTO membership. It also allows export to a number of non-WTO developing countries that are "low-income" without some of the additional requirements imposed in Canada's law.

- The EU regulation does not offer the possibility for non-governmental organizations or UN agencies to make use of the system, even though they are often the prime suppliers of medicines, unless they have the "formal authorization" of the government of the

importing country. This same unnecessary restriction was added at the last minute to Canada's law.

- As with the Canadian legislation, the EU regulation limits to 30 days the required period of first attempting to negotiate a voluntary licence with the patent-holder before a compulsory licence may issue. But it also goes further, by waiving this precondition in cases of compulsory licensing for "public non-commercial use" and "national emergencies and other circumstances of extreme urgency", something permitted under TRIPS that the Canadian law fails to include.

- The EU regulation also says that, in these circumstances of public non-commercial use or dealing with emergency or urgent situations, the maximum royalty payable to the patent-holder is 4% of the total price to be paid by the importing country for the EU-made generics – the same cap that is set across the board in the Canadian law. However, the EU regulation is less clear in that it simply says this is a maximum royalty rate, and is silent on how to determine the exact royalty rate applicable in the case of export to any given country, which uncertainty could be an important disincentive to generic manufacturers. Furthermore, the EU regulation does not set any cap on the royalty payable in other circumstances, although it does suggest the 4% figure could be used as a reference point, taking into account humanitarian considerations.

United States

Ironically, the country that has been one of the most ardent proponents of strict patent rules and has pressured other countries to eliminate or refrain from compulsory licensing, has itself regularly issued compulsory licenses. The case of threatening to override Bayer's U.S. patent on the antibiotic ciprofloxacin, during the October 2001 anthrax scare that raised fears of bioterrorism, is probably the most well-known case related to medicines. This incident was an important backdrop to the WTO negotiations that led to the 2001 Doha Declaration affirming the right of WTO member countries to use compulsory licensing. However, the U.S. applies a double standard when assessing its own national interest as compared to the health of patients in developing countries. Countries that have tried to limit or balance patents with other public policy goals such as access to medicines inevitably run into opposition from the U.S. as well as other rich nations, where powerful drug companies are based, including threatened or actual trade penalties.

The Doha Declaration states explicitly that all WTO member countries are free to decide the grounds on which compulsory licensing may occur. Yet, since the Declaration was adopted in 2001, the U.S. has negotiated various free trade agreements with developing countries that restrict the use of flexibilities under TRIPS. The U.S. pharmaceutical industry stands strongly behind these efforts. While the intellectual property provisions of these agreements vary in their specific terms, the U.S.'s common objectives are to limit the potential exclusions from patentability, to prevent parallel importation, and to limit the grounds on which compulsory licenses may be granted (such as allowing this only in "emergency" situations). In addition, the U.S. is negotiating for "data exclusivity" provisions preventing any use of scientific data submitted by the original patent-holding company in getting marketing approval. As explained above, this would preclude the simpler process of demonstrating a generic medicine's bio-equivalence to the already approved product, causing additional expense and delay in generic products entering the market. These U.S. proposals are aimed at eliminating flexibilities that exist under TRIPS, at least in theory.

Conclusion

The recent developments in countries such as India, Brazil and Thailand illustrate how access to lower-cost generic medicines could become dramatically more difficult in the coming years. The WTO Decisions of August 2003 and December 2005, ostensibly aimed at loosening the TRIPS patent rules to help secure access to medicines, are untested as yet and will be worth little if no further action is taken. New trade agreements that impose "TRIPS-plus" restrictions must be rejected. Governments must be willing to use compulsory licensing to secure lower-cost medicines for patients in their own countries and abroad, and make the necessary legislative changes that may be required in their domestic law. For those countries without domestic capacity to manufacture generics, it is important that supplier countries adopt legislation to allow easy compulsory licensing for export, learning from and improving upon models such as the legal reforms adopted in Canada, India, and other jurisdictions.