CANADIAN HIV•AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH•SIDA

Protecting global health & human rights:

Why and how the Patent Act should be amended to allow generic drug exports to developing countries

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The global gap in access to medicines
The vast majority of people living in developing countries have limited or no access to many medicines that have saved and extended the lives of those in wealthier countries. The World Health Organization (WHO) estimates ? of the world's population – some 2 billion people or more – lack regular access to essential medicines such as penicillin. Between 5 and 6 million people with HIV/AIDS in developing countries need anti-retroviral drugs (ARVs) now, but only 300,000 get them. In Africa, 1% of people with HIV get ARVs.

Why are cheaper, generic drugs needed?
Access to drugs depends on several factors. In the face of rampant global poverty, high drug prices are one key obstacle. The WHO reports that, in developing countries, most drug expenses are borne by patients and represent the major out-of-pocket health expense for poor households. The cost of medicines is simply out of reach for the vast majority of people in poor countries. And governments in developing countries have limited resources to spend on health. Those resources (including development assistance provided by countries like Canada) can go further if drug prices are lower.

Ensuring comprehensive, sustainable access to affordable medicines means overcoming this price barrier. Relying on companies' voluntary price reductions or drug donations is not sufficient. People's human right to health should not depend on charity. Governments must also promote access to medicines through their public policy. The WHO reports that competition from generic drugs is one of the most powerful tools for bringing down prices. Public pressure and global competition from generics have reduced the prices of AIDS drugs.

What are generic drugs?
Generic drugs are copies of patented, originator drugs, with the same therapeutic effect. They are sold when the original, brand-name drug is not under patent or if an authorizing license has been issued (see below). Canadians regularly use high-quality generic drugs, made by both domestic and foreign companies. They must meet the same quality standards as original brand-name drugs. They should not be confused with counterfeit drugs. The WHO runs a project to verify the quality of generic ARVs from various companies.

Why amend the Patent Act? Why now?
Canada has ratified international human rights treaties that commit us to helping achieve the highest attainable standard of health for all people, including by providing international assistance to other countries. The Prime Minister has stated Canada will work to ensure affordable, effective treatment is available to all in need.

In August 2003, World Trade Organization (WTO) countries agreed to allow more flexibility in patent rules, to make it easier for (some) developing countries to import generic drugs if they lack the ability to produce their own. While the deal creates unnecessary hurdles for countries wanting to use the process, it is still a step in the right direction. The deal removes any excuse for inaction by countries that can supply those drugs. Canadian generic drug companies have long requested permission to export medicines.

These developments have recently led the UN Special Envoy on HIV/AIDS in Africa, Stephen Lewis, to call on Canada and other G7 countries to allow their generic drug manufacturers to supply lower-cost drugs. In response, the government has committed to amending Canada's Patent Act, one important part of strengthening our overall response to global health challenges.

How does the Patent Act currently prevent exports of generic medicines?

Under the Patent Act (s. 42), only the company that holds the Canadian patent on a drug has the legal right to make (and sell) that drug in Canada while the patent is in effect (20 years). In other words, a patent gives the holder a monopoly on the drug. If a generic company manufactures its own version of the drug during the patent term, it can be sued for infringing the patent.

This ban on manufacturing a generic drug during the patent term applies even if the drug is intended for export outside Canada and the laws of the country receiving the drug allow for it to be imported and sold there. This prevents a Canadian company from making cheaper generic medicines to supply countries that can't afford higher prices charged by the patent-holder.

Do WTO rules prevent Canada from allowing exports of generic drugs?

No. As a WTO member, Canada ratified the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (or "TRIPS"), which requires Canada to give drug companies 20 years of patent protection with exclusive patent rights. But TRIPS also contains some flexibility for countries in deciding how to balance patent protection with health protection. There are two ways Canada can allow generic drug exports without breaching WTO rules.

(1) "Limited exceptions" to patent rights

First, TRIPS (Article 30) allows countries to legally define "limited exceptions" to exclusive patent rights. It would be simplest and most straightforward to insert such an exception in the Patent Act, allowing generic drugs to be made in Canada for export to another country where either (a) the drug is not patented or (b) if it is patented, that country's laws have, in some way, authorized the import and sale of a generic version. The Patent Act could be amended to state that manufacturing the drug in Canada in these circumstances does not amount to patent infringement.

(2) "Compulsory licensing"

Second, TRIPS (Article 31) also allows countries to override a company's exclusive patent rights by issuing a "compulsory licence" on a drug. This permits the government or another company to make, sell, or import the medicine without the authorization of the company holding the patent. Usually, efforts must first be made to get a voluntary licence on "reasonable" terms. (In an emergency situation, TRIPS allows countries to skip this step.) If this doesn't work, and a compulsory license is issued, the patent-holder is usually entitled to "adequate remuneration". Any royalty amount should be decided by the law of the country where the generic drug is sold.

Under TRIPS, countries are free to decide for themselves the reasons for issuing compulsory licenses. WTO countries have also unanimously adopted a *Declaration on the TRIPS Agreement and Public Health* (the "Doha Declaration") expressly confirming this right of sovereign countries. In the past, Canada used compulsory licensing regularly, stimulating the development of our generic drug industry. Canada could amend the Patent Act to allow for compulsory licensing to authorize generic companies to make drugs here for export to low- and middle-income developing countries.

This is possible because of the August 2003 agreement at the WTO to loosen restrictions on exporting generic versions of patented drugs. Under TRIPS, ordinarily a compulsory licence must be used "predominantly" to supply the domestic market of the country where the licence is issued. In other words, Canada could use compulsory licensing but only if it were predominantly to supply Canadians with generic drugs. This restricted the ability of a country to use compulsory licenses to allow production of generic drugs for export. And this, in turn, created a barrier for countries who cannot make their own drugs and so must import them – even if they issued a compulsory license authorizing imports of generic drugs into their country, potential suppliers in other countries (such as Canada) faced this restriction at their end in getting a compulsory license to make generic drugs for export. The recent WTO agreement is aimed at easing this restriction on generic exports.

But countries that can produce generic drugs must now take action. Canada's Patent Act currently has no provision that would allow either "limited exceptions" to patent rights in the case of exports of generic drugs, or the issuing of compulsory licenses allowing companies to make generic versions of patented drugs for export.

How should the Patent Act be amended?
The Patent Act should be changed to create a simple, efficient process for legally allowing the manufacture of generic drugs in Canada for export.

As explained above, the best option would be to create a **"limited exception"** to exclusive patent rights, to allow a generic drug to be made in Canada for export to a country where either (a) the drug is not patented, or (b) if it is patented, that country has taken advantage of TRIPS flexibilities to legally authorize the import and sale of a generic version in some way. Alternatively, Canada could introduce a system for generic manufacturers to obtain **compulsory licences** to make and export less expensive generic medicines. This would be more cumbersome.

Either way, at least 3 key issues must be addressed:

(1) Don't limit exports to "emergencies"
Some say that we should only allow generic drug exports to countries facing "health emergencies". Such a restriction is unjustified and unnecessary. How many people would have to be sick or die before something is considered an "emergency"? Who will decide? Canada and the US were prepared to override patent rights to get lower drug prices in response to the 2001 anthrax scare when a handful of people were sick. Why should we dictate to other countries needing to import less costly generic drugs how bad things must get before their people can get treatment? It is unethical to let people suffer unnecessarily, and waiting for a crisis before getting drugs to people is bad medicine and bad public policy.

Any such restriction would also be at odds with the WTO's own rules. Drug companies and some governments often assert that, under TRIPS, countries can only limit patent rights through compulsory licensing in "emergency" situations. This is not true. TRIPS has no such limitation on compulsory licensing. In fact, the Doha Declaration expressly confirmed that countries have full freedom to decide when to issue compulsory licences. And the recent WTO agreement on generic exports is not limited to just emergency situations, despite efforts by brand-name drug companies and some countries to impose this restriction. To legislate an "emergencies only" restriction on exports of generic medicines would be to impose an unwarranted, unethical double standard on poor countries.

(2) Allow exports for all health conditions
Over 42 million people worldwide have HIV. 95% of them live in developing countries. 28 million people have already died of AIDS. Every day, 8000 more die and 14,000 are newly infected with HIV. Malaria kills 1 million people each year, and is the leading cause of death in young children. Every year, 8 million people get active TB; someone dies of it every 15 seconds.

But we cannot ignore other health conditions. Cardiovascular disease kills 17 million people a year, 78% of them in developing countries. 177 million people in the world are diabetic, most in developing countries; this number is projected to rise to 300 million by 2025. The WHO estimates that 150 million people have asthma – again, mostly in developing countries. Some 80 million people in developing countries lack treatment for cancer.

Should someone get less expensive drugs if they have HIV or TB, but not if they have cancer, diabetes or asthma? It would be unethical to deny affordable medicines to people in poor countries because their health condition is not on an "approved" list. How can countries like Canada dictate that list to other countries? Which medicines enjoyed by Canadians should be denied to people in developing countries?

(3) Don't limit exports to only certain countries
Nor should we create an "approved" list of countries to which Canadian-made generic drugs can be exported. If a drug is not patented in a particular country, there is no basis for objecting to selling a generic version there. Or, if the drug is patented there, a compulsory license may have been issued, in accordance with that country's laws, to allow the import and sale of a generic version of that drug. In such a case, again there is no reason why Canadian law should stand in the way of generics being exported there. Remember that WTO countries have full freedom under TRIPS to decide when and how to use compulsory licenses. It is up to other sovereign countries to decide how to respond to the health needs of their people, and how to balance patent protection with protecting their people's health.

Are patents really blocking access to drugs?
Yes. A study often cited by brand-name companies claims patents are not a major barrier to accessing AIDS treatment in Africa. But the study data actually shows that ARVs are patented in countries with higher numbers of people with HIV/AIDS and higher (by African standards) incomes. Some of the most commonly used ARVs are patented in up to ? of African countries. Furthermore, ARVs must be used in combination. Yet important combinations – including single pill formulations for simpler dosing, particularly important in resource-limited settings – are widely covered by one or more patents. Limiting drug options in this way is bad medicine: treatment is less effective, sticking to dosing schedules is harder, and the chance of HIV becoming drug-resistant rises.

But what about inadequate health systems?
Safe and effective use of medicines not only requires that they be affordable; it also requires adequate infrastructure, such as clinics, trained health care workers, and equipment. But it is unethical and inaccurate to use generalizations about developing countries as an excuse to block access to more affordable, generic medicines. In many places, the existing infrastructure is adequate to deliver medicines, but their price keeps them out of reach. People die because they cannot afford to buy their lives. Where the infrastructure is inadequate, there is a need for both lower drug prices and for strengthening the health system. Doing nothing is not the answer.

Canada should not only support access to less expensive medicines. We also urge the government to live up to its decades-old promise to dedicate 0.7% of gross national product (GNP) to aid (including to improve health infrastructure), and to contribute to the Global Fund to Fight AIDS, TB & Malaria proportionate to our share of global GNP. Currently our annual contribution is about US$1 per Canadian, far below the fair share we can afford. A House of Commons committee has recommended Canada triple its Global Fund donation.

Can developing countries use HIV/AIDS drugs?
Yes. The WHO has issued simplified guidelines on using ARVs to treat people living with HIV/AIDS in "resource-poor settings". Brazil's program of distributing free ARVs (including locally produced generics) to over 100,000 people has cut deaths and hospitalizations from AIDS dramatically and saved hundreds of millions of dollars. A joint report from WHO and Médecins Sans Frontières documents the successful use of ARVs in 10 developing countries, and shows that countries that foster competition between generic and brand-name drugs have more affordable ARV prices. Recent studies show patients in several African countries are sticking to their AIDS drug regimens as well as, or better than, patients in developed countries. It is false to claim that medicines cannot be safely used in poor countries.

What about cheap drugs getting diverted?
Everyone should be concerned if cheaper medicines do not reach those in developing countries who need them. But brand-name companies over-state this concern in a misguided effort to block generic exports. Export controls and proper management of the supply chain can ensure drugs get to their intended recipients. Generic companies already produce their versions of drugs that have gone off-patent and package them differently. Border controls prevent these drugs sold abroad from showing up on street corners or in pharmacies in Europe and North America, with only the odd case of diversion.

What about drug research & development?
Brand-name companies say they will reduce spending on research and development (R&D) if we loosen patent rules. But allowing generic sales in developing countries poses no real risk to their profits and R&D incentive. All of Africa accounts for roughly 1% of global pharmaceutical sales, hardly much incentive for R&D. In fact, because poor markets offer little potential profit, companies do little research into diseases affecting mostly developing countries. The multi-national pharmaceutical industry – the world's most profitable – gets its profits from rich North America and Europe. Denying cheaper drugs to poor countries will not protect or stimulate R&D driven by profits in wealthy countries. It is fair that poor countries pay less for medicines, and rich countries pay more. But claiming that supplying less costly drugs to developing countries undermines incentives to invest in R&D is misguided.

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