

Intellectual Property Law and Global Access to Medicines

Case study: Reforming Canada's law on compulsory licensing for export

Canadian Conference on the Public's Health and the Law:
The Role of Law in Promoting and Protecting the Public's Health
-- Session on : "Access to Essential Medicines"

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Canadian
HIV/AIDS
Legal
Network

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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 HIV/AIDS.



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Outline

**Patents and access to medicines in international law:
health as commodity vs. health as human right**

International: key developments in WTO law (TRIPS)

Domestic: Canada's law on compulsory licensing for export

Health as a Human Right and access to medicines

WHO Constitution (1946)

Universal Declaration of Human Rights (1948)

Intl Covenant on Economic, Social & Cultural Rights (1976)

- CESCR General Comment No. 14 on right to health (2000)

Multiple UN declarations

- Vienna Declaration (1993)
- Millennium Declaration with MDGs (2000)
- UNGASS HIV/AIDS Declaration (2001)

UN Commission on Human Rights

- Resolutions on access to medicines
- UN Special Rapporteur on right to health

World Health Organization

- WHA resolutions on drugs
- Work on improving treatment access... eg. “3 by 5 Initiative”

UNAIDS & OHCHR

- International Guidelines on HIV/AIDS & Human Rights (1998, rev. Guideline 6 in 2002)



Health as a human right

- CHR Resolutions in 2001 – 2005 (and UNGA resolutions in 2003, 2006): access to medication is a fundamental element of progressively realizing the human right to the highest attainable standard of health
- International Guidelines on HIV/AIDS & Human Rights - Guideline 6 (rev September 2002): ensure trade agreements do not adversely impact on realization of right to health, including access to treatment



Health as commodity: WTO/TRIPS

Issue:

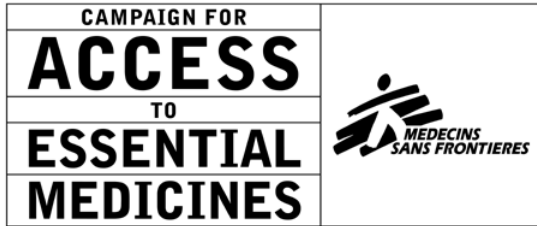
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) globalizes one approach to intellectual property (IP) rules
- IP regime is one factor determining costs of patented pharmaceuticals, and hence access to medicines, with variable effect depending on context and multiple other factors



Health as commodity: WTO/TRIPS

...drug prices are a critical determinant of access to health care. Patented drugs are substantially more expensive than generic versions. ... Several studies for developing countries have estimated the impact of patents on drug prices.... Their estimated increases range from 12 per cent to 68 per cent once TRIPS is implemented. In the case of anti-retroviral drugs for HIV/AIDS, patented drugs that cost US\$10,000-\$12,000 per patient per year are available for US\$200-300 in their generic form...

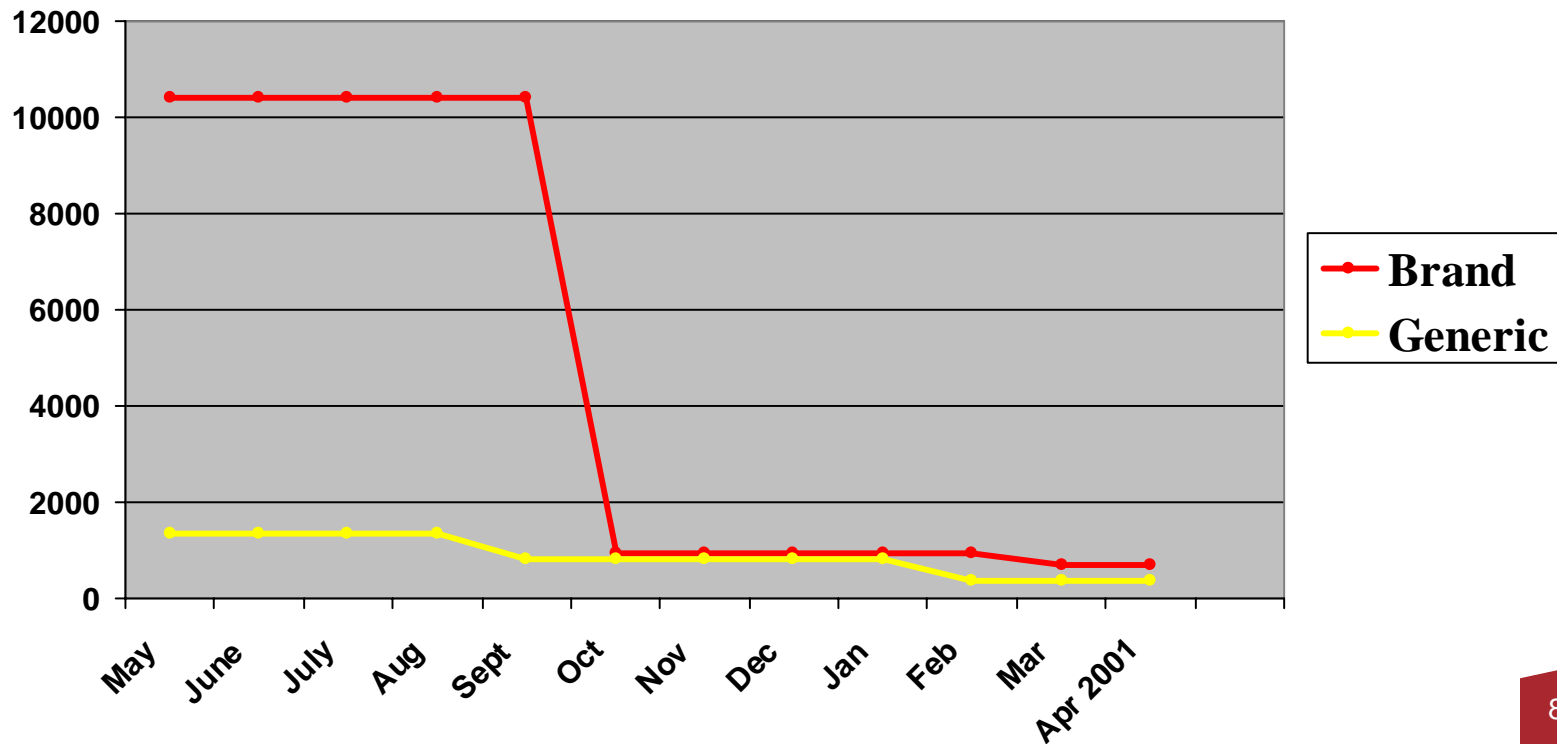
- UN Development Programme,
Making Global Trade Work for People (2003)



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Effects of Generic Competition on Price and Drug Access

Sample AIDS triple-combination: lowest world prices for stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP)



TRIPS - Law

Questions:

- What does TRIPS require?
- How to balance interests in public policy?

“odd treaty out” in WTO system:

- not a trade liberalization treaty
- minimum domestic standards re: intellectual property
- “revolution” in international trade law

staggered compliance dates

- Developed countries... Jan 1/1996
- Developing countries...Jan 1/2000
 - until 2005 for pharmaceutical products if not previously patentable
- Least developed countries...Jan 1/2006
 - Doha extension re: pharmaceuticals to 2016 (general extension to 2013)



TRIPS - Law

Key provisions:

- Art 28... exclusive patent rights
- Art 33... minimum 20 year term
- **Art 30... limited exceptions**
- **Art 31... other use (compulsory licensing)**
- Art 6... parallel importing permissible

- Art 7... objectives
- Art 8... principles

TRIPS - Application

Developed country: Canada and effort to claim TRIPS flexibilities

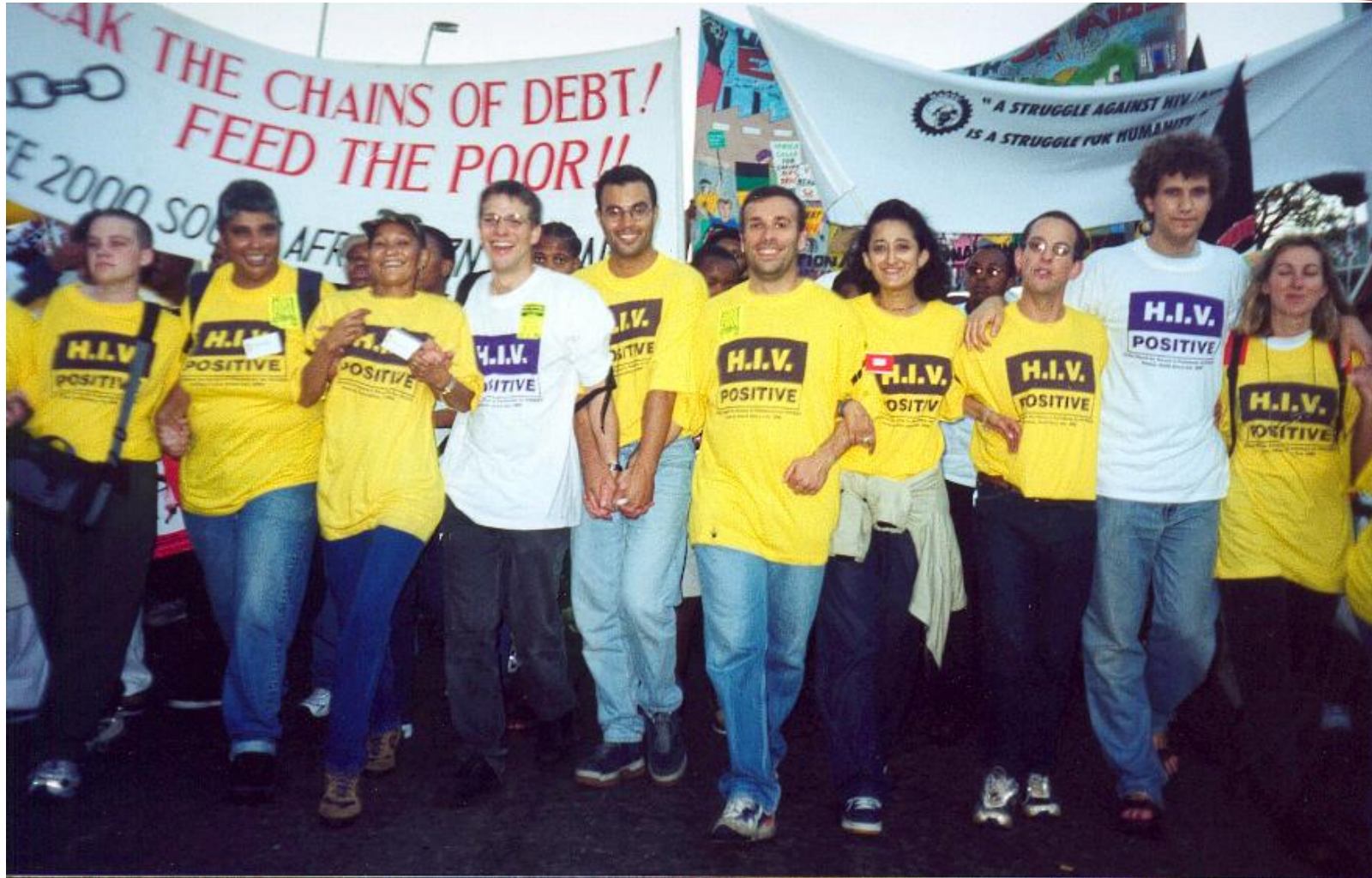
- *Generic Medicines* case (2000, WTO Panel ruling)
 - “regulatory review” exception
 - “stockpiling exception”
 - Canada’s public interest arguments re: interpretation of Article 30 (“limited exceptions” to exclusive patent rights)
 - WTO Panel’s interpretation → creation of additional market monopoly period, contrary to explicit text of TRIPS and DSU Article 3.2
- Future interpretation of TRIPS (particularly Article 30)?
Generic Medicines decision vs. Doha Declaration... and role of IHRs law?

TRIPS - Application

Developing countries

- WTO dispute settlement proceedings
 - India: “mailbox” provision re exclusive marketing rights

- Political use of TRIPS
 - South Africa... PMA v. RSA case (1997-2001), global campaign, use of law as strategic advocacy tool (TAC intervention)
 - Brazil: local working requirements, dispute put on hold June 2001
 - Multiple other countries...eg, Thailand, Cambodia’s WTO accession





TRIPS – Global debates

- WTO Africa Group & other developing countries put issue on TRIPS Council agenda, June 2001
- pre-Doha, Sep/Oct 2001.... “cipro affair” in US & Canada... threats of compulsory licensing
 - “These are extraordinary and unusual times. Canadians expect and demand that their government will take all steps necessary to protect their health and safety.”
Health Canada spokesperson, *New York Times*, 19 Oct 2001



TRIPS – Global debates

- **WTO Doha Ministerial (Nov 2001): Declaration on the TRIPS Agreement and Public Health**

Para 4: TRIPS Agreement “can and should be interpreted in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”

Para 6: difficulties in “making effective use of compulsory licensing” for countries with insufficient or no manufacturing capacities in pharmaceutical sector” (the Article 31(f) problem)...solve by end 2002 [final text agreed 30 Aug 2003]

Doha Para. 6 problem

- Compulsory licenses serve dual function of
 - (a) permitting production or importation of products under patent
 - (b) providing leverage in price negotiations as “background” possibility, or explicit lever (e.g., U.S.-Bayer/Canada-Bayer cipro negotiations or Brazil-MNC ARV negotiations).
- Problem: combination of expiration of TRIPS Agreement transition period for granting pharmaceutical patents and Article 31(f) limitation on compulsory licensing for export
- As of 1 Jan 2005, world supply of off-patent (generic) medicines will contract as mailbox applications processed and new medicines under WTO-wide patent.
- **For compulsory license issued under Article 31, TRIPS Agreement says: “(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”**

TRIPS – Global debates

Post-Doha

- LDC extension to 2016 re patent protection (WTO TRIPS Council, June 2002)
- LDC waiver until 2016 re exclusive marketing rights (WTO General Council, July 2002)
- Art. 31(f) problem (Doha para 6)
 - efforts to restrict “solution”
 - US blocks deal in Dec 2002
 - *August 30, 2003 decision adopting solution in form of “interim waiver”*
 - *Accompanied by WTO General Council Chairperson’s Statement*
 - December 2005 “permanent amendment” replicating Aug 2003 waiver

Canada's law on compulsory licensing for export

- Civil society campaign: Sep 2003 – May 2004
 - September 2003
 - CGPA letter to Int'l Trade Minister
 - Canadian NGO calls for amendment as per Aug 30 WTO text
 - UN Special Envoy on HIV/AIDS in Africa takes up call
 - Government commitments
 - Ongoing campaigning
 - NAFTA hurdle? ... resolved with US/Canada exchange of letters
 - Initial signals re: restrictions on scope, delay by government
 - Ongoing campaigning... through change in governing party leadership, spanning two sessions of Parliament, SCIST hearings, multiple amendments
- Passage of *Jean Chrétien Pledge to Africa*: royal assent on 15 May 2004
 - Proclaimed in force May 2005, regulations published 1 June 2005



Canada's law on compulsory licensing for export

“The full impact of the agreement will depend on how effectively it can be implemented in countries. ... WHO continues to urge Member States to consider using to the full the TRIPS flexibilities with regard to the protection of public health.”

- WHO Statement on WTO access to medicines decision, 1 Sep 2003

“It will be a ‘negative black eye for Canada’ that will ‘very well affect the investment climate’.”

- Harvey Bale, Director-General, IFPMA, Globe and Mail, 27 Sep 2003

Canada's initiative is “a smart response.... [T]he first major move by a major, industrialised country to overcome a key structural hurdle in getting life-saving medicines to people who desperately need them.”

- Carol Bellamy, UNICEF Executive Director, 29 Sep 2003

“We strongly believe that if properly implemented, this brave step will make a significant contribution towards ensuring a sustainable supply of affordable essential medicines in the developing world.”

- Treatment Action Campaign & AIDS Law Project (SA), 1 October 2003

Canada's law on compulsory licensing for export

How does the *JCPA* work?

- Generic manufacturer & developing country purchaser strike a tentative deal → specific drug, specific quantity, specific price, time frame
 - if NGO is purchaser, need “permission” of government of importing country
- Generic manufacturer goes through Health Canada TPD review
 - Only required for drugs exported under JCPA
 - “Fast-track”...?
 - Review of product for which no existing comparator (e.g., FDCs)?
 - Includes review of required features differentiating generic from patentee's product marketed in Canada
- Generic manufacturer requests VL from patentee(s) based on single contract
 - disclosure of country and quantity
 - 30 day period for negotiation on “reasonable commercial terms and conditions”

Canada's law on compulsory licensing for export

How does the *JCPA* work? (cont.)

- If VL negotiation unsuccessful, generic can apply to Commissioner of Patents for compulsory license
- If statutory conditions satisfied, Commissioner “shall” issue non-exclusive license to applicant
 - Royalty payable is set by regulation: sliding scale linked to importing country's HDI ranking, max 4% cap (although patentee may apply to Federal Court for higher royalty)
 - License permits export only of quantity set out in application (i.e., quantity originally negotiated by generic with purchaser)
 - Maximum 2 year term for compulsory license
 - For each shipment, postings to website and info to patentee(s), importing country government, purchaser
- Importing WTO Member must notify TRIPS Council of intention to use Aug 30, 2003 mechanism, lack of manufacturing capacity, and either no patent or intent to issue CL

Canada's law on compulsory licensing for export

Limitations of *JCPA*

- Chicken-or-egg: contract as basis for seeking VL/CL to export, but no guarantee can supply without license
- NGOs require “permission” of importing country government
- Schedule 1: limited list of products; Ministerial, Cabinet decisions to add
- Schedule 3: non-LDC, non-WTO developing countries (ODA-eligible per OECD) face unjustified, additional conditions:
 - “national emergency or other circumstances of extreme urgency”
 - pledge to not permit “commercial use”
- VL negotiation precondition
 - risks to countries of pressure, retaliation
- CL is for specific quantity to specific country/purchaser only
- Arbitrary 2 year limit on compulsory licences; new application required; limits commercial viability, economies of scale
- Caps on prices/profit margins, invitation to vexatious litigation by patentees



Canada's law on compulsory licensing for export

Recommendations for reform

- Abolish Schedule 1; permit CL for “any pharmaceutical product”
- Eliminate additional requirements for non-LDC, non-WTO developing countries
- Eliminate requirement for “permission” for NGOs
- Eliminate HC approval as requirement for CL for export
 - accept either HC or WHO Prequalification Project approval; or
 - simply let importing country decide what standard required
- Waive VL negotiations at least in cases of emergency/extreme urgency, public non-commercial use, or remedying patentee's anti-competitive practice
- Eliminate arbitrary limit on term of CL
 - remaining term of patent, or alternatively at least coterminous with contract that is basis for CL application
 - easy process to extend existing CL (add to existing contract, new contract)



Canada's law on compulsory licensing for export

Recommendations for reform

- WTO August 30, 2003 mechanism is more fundamental problem
- Legislate streamlined process:
 - Compulsory license automatically at outset of process
 - Condition: disclose contracts and pay royalties on any contracts negotiated as per existing JCPA formula
 - Eliminates VL negotiations, risky disclosure of country
 - Longer-term, multiple-purchaser contracts → economies of scale
 - Flexibility for manufacturers and purchasers (e.g., adjust quantities, countries as needed)



Canada's law on compulsory licensing for export

Recommendations for reform

- Such a scheme is WTO-compliant
- Aug 30, 2003: “without prejudice to other TRIPS rights and flexibilities”
TRIPS Article 30: *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.”
- TRIPS Article 1: WTO members free to determine appropriate method of implementing TRIPS within own legal systems and practice
- Doha Declaration (2001): TRIPS can and should be interpreted and implemented so as to protect public health and in particular to promote access to medicines for all; WTO members have right “to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”

“People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off.”

- Kofi Annan, UN Secretary-General, 2001

“Health equity is best thought of not as a social goal in and of itself, but as inherently embedded in the pursuit of social justice.”

- Evans et al, 2001

“We are angry. Our people are dying.”

- Pan-African HIV/AIDS Treatment Access Movement,
Declaration of Action, Cape Town, 25 August 2002



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