UNIVERSITY OF SASKATCHEWAN



The Jean Chrétien Pledge to Africa: **Canada's Role in Access to Affordable Medicines**

BACKGROUND

- The goal of patent protection is to encourage invention and innovation
- In exchange for granting a monopoly of proprietary rights to the inventor, the public is permitted to use these creations; this is the patent quid pro quo
- However, the exclusivity provided by patent protection may also confer market power for the patent holder
- The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was created between member nations of the WTO in order to introduce an intellectual property law regime annexed to an international trading regime
- Countries wanting access to the world trade market must also adopt an intellectual property regime – often requiring large reorganization of existing laws and adoption of an IP regime not well suited for developing and least developed nations
- Access to patent-protected pharmaceuticals became difficult for those countries unable to produce but also unable to import these expensive medicines
- WTO relaxed some restrictions in 2003 under the Doha Declaration to allow developing/least developed countries unable to produce pharmaceuticals to get a compulsory license to import on-patent medicines
- Canada was the first to amend its *Patent Act* to implement this decision

ISSUES

- 1. How does the regime impact the ability of developing and least developed countries to access medicines required to fight epidemics such as HIV and AIDS?
- 2. What effect has Canada's amendment to the Patent Act had on fighting these epidemics?

Figure 1



HIC = High Income Countries; LMIC = Low Income Countries DALYs = Disability Adjusted Life Years: The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability. HIV is an acute condition, but also considered chronic since there is no cure

Kirsty Vogelesang

FINDINGS

Problems with Canada's Access to Medicines Regime:

- "among the most bureaucratically complex pieces of legislation administered by the Canadian Intellectual Property Office"¹
- brand name company can revoke the license at anytime, or make the negotiation process so slow as to be inhibitive
- several of the requirements under the process are over and above the requirements of TRIPS
- generic company must release the name of the intended importing country; a huge obstacle for countries fearful of trade sanctions and pressure from the developing world (the US in particular)
- limit of 2 years for the compulsory license authorizing exportation
- fixed "maximum quantity" for the drug being exported generic manufacturer has to file multiple separate applications for each country, each drug, and each quantity being produced
- Other countries can offer medications cheaper and easier than what CAMR can
- And many more ...

Has the regime ever been used?

- First, and only, instance of this provision being utilized was in 2007 when Rwanda made an application for importing an HIV antiretroviral drug treatment
- The whole process took 3 years before Rwanda received the medications Apotex gave press release indicating it would not seek renewal
- No other applications under CAMR since then

Figure 2



17.6% of the world's in low income countries = mere 1% of global pharmaceutical expenditure

POTENTIAL ALTERNATIVES

- Reform the JCPA to remove some of the cumbersome bureaucratic hurdles
- Brazil aggressively negotiates with brand name pharmaceutical companies to drive down prices of anti-retrovirals – threats of compulsory licensing are compelling
- Tax deductions might incentivize the brand name companies to offer at lower cost without the cumbersome compulsory license process under CAMR – or even incentivize generic companies to participate
- Allow NGOs, not just generic companies, to obtain lower cost generics voluntary licenses are compelled by settling with the Competition
- Competition law framework such as that in South Africa where Commission

Figure 3

Canadian Manufacturer's Sales of Patented and Non-Patented Drugs from 2004 to 2015 (Sales in \$ billions)			
Year	Patented	Non-Patented	Total
2004	11.0	4.2	15.2
2005	11.5	4.8	16.3
2006	11.9	5.7	17.6
2007	12.3	7.2	19.5
2008	12.6	7.8	20.4
2009	12.9	8.9	21.8
2010	12.4	9.7	22.1
2011	12.8	9.0	21.8
2012	12.8	8.8	21.6
2013	13.3	8.6	21.9
2014	13.7	9.3	23.0
2015	15.2	9.4	24.6

- on meeting this global health care dilemma
- of Industry to improve its efficacy

Figure 1: Kaplan, W. and Mathers, C. (2011) The World Medicines Situation 2011, Global health trends: global burden of disease and pharmaceutical needs. 3rd Edition, World Health Organization, Geneva, Figure 1.2, page 7. Figure 2: Lu, Y. Hernandez, P. and Abegunde, D. (2011) The World Medicines Situation 2011, Medicine expenditures. 3rd Edition, World Health Organization, Geneva, Figure 1.1, page 5. Figure 3: Canada, Industry Canada, Pharmaceutical industry profile, April 2014 Canada, update Industry 2014) online: (Ottawa, <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html> ¹Tania Bubela, E Richard Gold & Jean- Frédéric Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence" (2011) 4:2 McGill J L & Health 4 at 14.

ACKNOWLEDGEMENTS

I would like to thank Dr. Thomas Roberts for his assistance in writing the accompanying minor paper and piquing my interest in Intellectual Property



CONCLUSIONS

Stronger patent protection can have a negative impact on access to affordable medicines in developing and least developed countries

CAMR has fallen flat on its promises to fulfill the Doha Declaration

• Despite CAMR's flaws, there appears to be no initiative by the Ministry

• Compulsory licenses can still be effective part of solution – but other routes besides the *Patent Act* amendments might be more successful

REFERENCES