



# *Access Strategies: Compulsory Licensing*

*Peter Maybarduk*

*Essential Action*

*maybarduk@gmail.com*



# *Compulsory licensing*

- ✧ What happens when we can't get the EAL or another voluntary license that we want?
- ✧ How can UAEM extend its mission beyond lobbying universities?
- ✧ How can students help in the broad struggle for access to medicines?



# Access

- ✧ Access to medicines is disparate within and between countries (access gap exists within nations and between nations).
- ✧ Does not correlate perfectly to income disparity.
  - ✧ [http://data.unaids.org/pub/Presentation/2006/20061128\\_la.pdf](http://data.unaids.org/pub/Presentation/2006/20061128_la.pdf)
- ✧ AIDS treatment rate in Nicaragua and Dominican Republic under 20%
- ✧ Brazil and Cuba boast AIDS treatment rates well over 80% despite relatively low GDP.



# Access

✧ Government-sponsored universal treatment programs provide the drugs, but the real key—and the reason poor countries can afford to treat their citizens—is availability of low-cost generic medicines.

✧ E.g., Five Years After Doha, Drug Prices are on the Rise, Doctors Without Borders Access to Medicines Campaign news release, Nov. 14, 2006, available at:

[http://www.accessmed-  
msf.org/prod/publications.asp?scentid=1411200692472&contenttype=PARA&](http://www.accessmed-msf.org/prod/publications.asp?scentid=1411200692472&contenttype=PARA&)



# *Generics*

- ✧ In the last ten years, generic antiretrovirals have fueled a revolution in AIDS treatment, providing life-sustaining drug regimens to 2 million people in developing countries who previously could not afford them (MSF/WHO).
- ✧ Generic competition drives down the price of brand-name drugs, and enables governments and international organizations to purchase many more drugs for their growing free treatment programs.



# *Patents and monopoly power*

- ✧ May confer monopoly power
  - ✧ Sometimes generics remain in the market
- ✧ Firms intensify global patenting and patent enforcement with time
- ✧ Unlike some monopoly markets, patents legally bar potential competitors from entry.
  - ✧ Even if firms can afford the startup costs and believe a profitable market awaits, they cannot enter the market until expiration of the patent's fixed, but entirely arbitrary, twenty-year term.



# *Busting the patent trust*

- ✧ Traditional economic analysis offers a simple solution to failing monopolized markets in essential goods with absolute barriers to entry: bust the trust, and let the market work.
- ✧ Fortunately, international law provides the same, in the form of a yet underutilized tool called a compulsory license.



# *Compulsory Licensing*

- ✧ Governments can authorize generic competition for products while they remain on patent.
- ✧ Reduces prices and promotes public access to medicines by creating competition in the market for a particular drug.
- ✧ These products may be produced locally or imported, conditioned only on payment of a reasonable royalty (roughly 4 percent or less).



## *Example: Malaysia*

- ✧ 2003: Malaysia issued “government use” compulsory licenses on three patented AIDS medicines, and began importing generic versions of the drugs from India.
- ✧ Reduced the cost to Malaysian Ministry of Health of treating an HIV/AIDS patient by 81% -- from \$315 to \$58 per month.
- ✧ Savings enabled Malaysia to increase number of HIV/AIDS patients treated in government hospitals from 1,500 to 4,000.
- ✧ Ling, Chee Yoke, *Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the Government Use Option*, Third World Network, at 5.



# *Savings*

- ❖ High-quality generic medicines are routinely available at savings between 30 and 98 percent
  - ❖ imatinib (Glivec by Novartis)
- ❖ Open license competition yields further price reductions from generics producers



## *Ejemplo: Brasil*

- ❖ 2001: Brasil anuncia está considerando las licencias obligatorias para efavirenz y nelfinavir
- ❖ March 2001: Merck ofrece descuentos para efavirenz
- ❖ August 2001: Merck ofrece descuento de 40% para nelfinavir



## *Ejemplo: Brasil*

✧ 2003: lopinavir, efavirenz, nelfinavir

✧ 2005:

✧ Kaletra (Abbott) – resulta en descuento de 46%

✧ Viread (Gilead) – 50%

✧ imatinib (Glivec, Novartis) - 65%



## *Ejemplo: Brasil*

- ✧ 2007: 75.000 de los pacientes brasileros con SIDA estaban tomando Efavirenz
- ✧ Merck/BMS: \$1.59/día en Brasil
- ✧ Genéricos: cerca de \$.45 por día
- ✧ La competencia genérica puede llevar los precios de Efavirenz bajo \$.25 por día.



## *Ejemplo: Brasil*

- ✧ 25 de abril de 2007: el Ministro de Salud José Gomes Temporão, firmó el decreto 866, declarando que la medicina efavirenz para el SIDA es de interés público.
- ✧ 4 de mayo de 2007: Brasil otorga la licencia obligatoria a través de un decreto firmado por el Ministro y el Presidente Lula



## *Additional examples*

- ✧ In recent years Indonesia, Mozambique, Zimbabwe, South Africa, Zambia, Eritrea, and Thailand have each issued compulsory licenses to promote access to medicines.
- ✧ Indeed, governments of many countries, including the United States, use compulsory licenses in a wide variety of circumstances.



## *Example: United States*

- ✧ In 2006 alone, at least four U.S. courts issued compulsory licenses on medical, software and engineering patents to remedy anticompetitive business practices.
- ✧ The United States routinely issues compulsory licenses for use of patented inventions by the government or its contractors, especially, but not only, in the defense sector.
  - ✧ As early as 1952, U.S. Supreme Court granted the “well-recognized remedy” of CLs in antitrust actions (*US v. Besser Mfg. Co.*, 343 U.S. 444, 447).



# *Compulsory licensing is a right*

- ✧ WTO's Agreement on Trade Related Aspects of Intellectual Property (TRIPS) guarantees Members' rights to issue compulsory licenses for the importation, manufacture and sale of medicines.
- ✧ Countries are free to issue compulsory licenses on whatever grounds they choose
  - ✧ Article 31, "Other Use Without Authorization of the Patent Holder."



# *The Doha Declaration*

- ✧ 2001 Doha Declaration on the TRIPS Agreement and Public Health
- ✧ Unanimously adopted by all WTO member states.
- ✧ “Each Member has the right to grant compulsory licenses and the freedom to determine grounds upon which such licenses are granted.”
- ✧ Paragraph 5(b)



# *The Doha Declaration*

✧ “The [TRIPS] agreement 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.”

✧ Paragraph 4.



# *Compulsory licensing is a right*

✧ On its Frequently Asked Questions page, the WTO calls the idea of an emergency requirement “a common misunderstanding.”

✧ [http://www.wto.org/English/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/public_health_faq_e.htm)



# *Compulsory licensing is a right*

- ✧ Article 31(b) requires governments to negotiate for an adequate voluntary license before deciding to issue a compulsory one, but creates broad exceptions.
- ✧ emergency or extreme urgency, which governments have the right to define
- ✧ non-commercial (government) use. Can manufacture, or authorize companies to manufacture, medicines to be distributed to the public through government agencies
- ✧ anticompetitive practice (31(k)).



# *Compulsory licensing is a right*

- ✧ TRIPS Article 31(f) initially limited countries' capacity to *export* drugs manufactured under CL
- ✧ Waived by August 30, 2003 order of WTO General Council.
  - ✧ WTO's solution is too complicated
- ✧ Canada-Rwanda
- ✧ We need better implementing legislation
- ✧ But the “paragraph 6” problem does not restrict CLs for products not on patent in their country of origin



## *Andean Community Decision 486*

- ✧ Establishes a common intellectual property regime for its member countries
- ✧ Terms are more restrictive than TRIPS
- ✧ Reasons of “public interest, emergency or national security”
- ✧ Reducing the price of medicines clearly qualifies



# *Bolivia*

- ✧ No tiene una ley doméstica de propiedad intelectual
- ✧ ADPIC junto con la Decisión 486 norman la licencia obligatoria en Bolivia



# *Ecuador*

- ✧ Ley de Propiedad Intelectual del Ecuador (1998)
- ✧ permite licencias obligatorias en el contexto de términos más estrechos en comparación con los ADPIC o la Decisión 486



# *Ecuador*

- ❖ declaración por parte del Presidente (Art.154)
- ❖ Seis meses contados a partir de solicitar una licencia voluntaria antes de otorgar la licencia obligatoria



# *Problems to solve when issuing a CL*

- ✧ Identify needed / problem products
- ✧ Identify patented products
  - ✧ We need better patent disclosure systems
- ✧ Drug registration / prequalification
- ✧ Economies of scale
  - ✧ regional registration systems could help
- ✧ Regulations / enabling political action
- ✧ Political will



## *Countries should:*

- ✧ Enact the most flexible domestic compulsory licensing laws possible
- ✧ Recognize and weigh the value of compulsory licensing before restricting CL rights in a trade or integration agreement
- ✧ Analyze laws, understand methods & grounds for CLs
- ✧ Work with other governments, agencies & NGOs to build support & expertise
- ✧ Consider issuing CLs sooner rather than later



## *Strategic value of CLs*

- ✧ Each license:
  - ✧ Saves lives and improves public health
  - ✧ Sets a precedent; easier for next country to do same
  - ✧ Pushes international norms toward protecting public health before IP.
- ✧ Mere threat of a CL can improve bargaining position.
  - ✧ If we can make CLs common, it will provide a powerful incentive for companies to negotiate more equitable license terms at the outset



# *What can students do?*

- ✧ Press for better university licensing agreements
- ✧ License to patent pools
- ✧ Support countries that exercise their flexibilities
- ✧ Support legislation to defend and facilitate TRIPS flexibilities
  - ✧ S. Res 241/H. Res 525
- ✧ Monitor university product developments; engage before licensing agreements are made
- ✧ Collaborate with NGOs: conduct research and support advocacy efforts