Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

Topic 4: Overview of the Use of Patent-Related Flexibilities and the Main Constraints thereon within the Region

Durban, South Africa
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Public health related aspects of intellectual property rights

Regional Seminar on Patent-Related Flexibilities

Dr. Peter Beyer

World Health Organization
Framework for access to medicines

1. Rational Selection and use
2. Affordable prices
3. Sustainable financing
4. Reliable supply systems

ACCESS TO ESSENTIAL MEDICINES
Rational selection of medicines

WHO Essential Medicines List

- 1977 - First edition
- Revised every two years
- Now contains more than 400 medicines including children's medicines
- Patent status NOT considered in selection

Affordability: no. of days wages, lowest paid govt. worker, to buy 7 day course ciprofloxacin 500mg tab twice daily, private sector

Source: Health Action International
www.haiweb.org
Affordable Prices


Global snapshot 11 May 2010
Average price US$ 10ml traditional vial soluble human insulin 100IU/ml, private sector
Eli Lilly brand
The case of HIV/AIDS

Access to antiretroviral (ARV) therapy in low- & middle-income countries:

2003: 400,000 patients

2011: 8 million patients

In need of treatment: 15 million (target 2015 - UN Political Declaration on HIV/AIDS)

May increase with future revisions of treatment guidelines
Prices and sources of ARVs

2000: first-line ARVs cost over US $10,000 per person/year

2010: median price of ten most widely used first-line regimens is about US $121 per person/year

Price reductions are the result of:

- Competition with and among generic producers
- Increasing market size due to the financial engagements of donors and national governments in financing procurement of HIV/AIDS treatment in developing countries

Generic vs. originator ARVs in quantities sold (%) (WHO Global Price Reporting Mechanism)
Prices and sources of ARVs

The role of Indian generic antiretroviral producers:

- 80% of the donor-funded developing country market
- In 2008: 87% of ARV purchase volumes; paediatric market 91% of purchase volume

Possible as many of the current ARVs are not patented in India

Brenda Waning, Ellen Diedrichsen, Suerie Moon, A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries, J Int AIDS Soc. 2010; 13: 35.
Outline

Introduction
Basics on access to medicines
Special case of HIV/AIDS
WTO/TRIPS Agreement
WHO Resolutions
Global strategy and plan of action on public health, innovation and intellectual property

The Sixty-first World Health Assembly,

Having considered the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property;¹

Recalling the establishment pursuant to resolution WHA59.24 of an intergovernmental working group to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, an enhanced and sustainable basis for needs-driven, essential health

WHA 62.16  2009  GSPA PH, Innovation & IP
WHA 63.28  2010  Establishment of CEWG on financing of R&D
WTO/TRIPS Agreement & Public Health

- TRIPS sets up the minimum criteria for patent protection countries have to implement through national legislation

- With regard to pharmaceuticals requires:
  - both process and product patents (previously no harmonization)
  - minimum patent term: 20 years (previously no harmonization)
  - protection of undisclosed information against unfair commercial use and disclosure (some precedents in Paris Convention)

- TRIPS provides for a number of public health-related flexibilities and safeguards
What kind of options do countries have?

TRIPS provides for public policy options/flexibilities that can help increase the availability of essential medicines, including:

- choices on grounds for compulsory licences/government use
- limited exceptions to exclusive rights (research/Bolar exemption)
- possibility to allow for parallel importation
- discretion as to how to apply patentability criteria (novelty, inventive step and industrial applicability)
- discretion as to how to provide for test data protection
- pre-grant and post-grant opposition procedures
How have flexibilities been used?

Research exemption

- **E.g. Switzerland**: research exemption, allowing all research and experimental projects access to information about the patented invention and its possible uses, including for research with a commercial background as its final purpose.

Bolar exemption

- **E.g. South Africa/Egypt**: starting manufacturing on a non-commercial scale during patent period for purpose of market authorization; not considered a patent infringement.
How have flexibilities been used?

**Compulsory licenses**

- E.g. **Brazil**: threat to use compulsory licensing lead to significant price reductions of key antiretrovirals; compulsory license for efavirenz in 2007

**Government use**

- E.g. **Indonesia**: in 2012 issued government use declarations for seven treatments for HIV/AIDS and Hepatitis C
How have flexibilities been used?

Pre-grant opposition procedures

- India: patent applications for antiretrovirals were rejected based on pre-grant oppositions

Patentability criteria:

- India: applications were rejected for lack of innovative step as known substances are not considered novel under the Indian Patent Act (paediatric formulations, heat stable versions)
Conclusions and Outlook

- Intellectual property is one determinant for access to medicines

- Prices of ARVs continue to decrease globally, but not for all treatment regimens - continued challenge for scaling up treatment coverage

- Financial commitment at governmental level is needed to sustain supplies of ARVs
Conclusions and Outlook

- Successes in increasing access to ARVs rely on Indian generics – will this be possible in the future?
- WTO/TRIPS agreement provides flexibilities to increase access to medicines
- Pharmaceutical companies are increasingly using non-exclusive license agreements in the area of HIV/AIDS
- Countries need to identify strategies to deal with access to high priced medicines
Public Health & Intellectual Property

Further information:

Dr. Peter Beyer
beyerp@who.int

WHO Department of Public Health, Innovation and Intellectual Property:

http://www.who.int/phi