Managing Procurement and Logistics of HIV/AIDS Drugs and Related Supplies

Intellectual Property Rights

Patrick Osewe
Senior HIV/AIDS Specialist
World Bank
Presentation Outline

• What is IPR
• Categories of IPR and IPRs in medicines procurement
• National law and international agreements
• Doha declaration
• Importance of understand the rules
• Features of international IPR systems
• Least developing/developing countries
• Government use and parallel importation
• Differential pricing
• Case study
What is IPR

- IPR are rights given to persons over creations of their minds
- The product should be unique and un-obvious with some value in the market.
- Gives the creator an exclusive right over the use of the creation for a certain period of time
Categories of IPRs

Trademark: a right granted to exclude others from the use of a sign that creates confusion in distinguishing the goods or services of one enterprise from those of other enterprises (e.g., Coca-Cola)

Copyright: right granted to author of “expressive” work (e.g., book or song) to prevent others from copying and distributing

- No protection for technical information or data
- Patient brochures accompanying medicine (such are not protected)
Categories of IPRs (cont.)

Patent: a right granted to the inventor of a new product to exclude others from its making, using, selling, offering for sale or importing for up to 20 years from date of application

Rights in Data: Protection against “unfair commercial use” of data submitted for marketing approval of new chemical entities
The Two-Fold Nature of IPRs

- IPRs such as patents are used to encourage research and development of new medicines by providing higher than competitive-market rate of return.

- Higher prices present procurement authorities with limited budgets as patients cannot afford expensive new drugs.
Principal Worries of patent holders

- Registration and authorisation concerns
  - Every country requires that pharmaceutical products should first be registered or submitted for commercialization authorisation with a national or regional regulatory body.
  - Although the goal of this process is to ensure the biosafety and bioequivalence of a generic version of a drug, it may be tedious and costly.

- Concerns about the adequate protection of submitted undisclosed information in the process of registration.

- Possible violations of patents, trademarks and copyright.
Principal concern(s) of governments and supply agencies

- IPRs system and particularly, patents, restrict access to essential medicines against HIV/AIDS especially in the poorer regions due to the high prices
- Patents promote monopoly & secrecy of information
- IP and patents may be a barrier to public health objectives
IPRs in Medicines Procurement

- IPRs provide the basis for “market exclusivity” in medicines and related supplies
- Market exclusivity directly affects the price and availability of medicines
- IPRs holders view strong enforcement of market exclusivity as important to profitability and will act to defend their interests
- Procurement specialists should understand the “flexibilities” afforded under international agreements and national law that can be used to reduce the impact of market exclusivity on affordability and access
National Law & International Agreements

- Each country or region has its own set of IPRs laws and regulations
- In-country legal situation that affects procurement authorities
- On January 1, 1995 the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") entered into force
- The TRIPS Agreement provides the basis for member countries to make claims against each other at the WTO
- TRIPS Agreement rules do not directly apply in most national legal systems, but instead are implemented by legislation
The TRIPS Agreement

- Establishes minimum standards of IPRs protection for all member countries of WTO

- Provides various “transitional arrangements” in favor of “developing” and “least developed” members

- Recognizes that IPRs protection must be balanced against public health needs

- Unjustified application of TRIPS rules led developing countries to demand that the WTO affirm the right to use the “flexibilities” built into the Agreement and negotiate important new flexibilities
The Doha Declaration

- Each country can determine if a national emergency or circumstance of extreme urgency exists
- Recognizing that HIV/AIDS may constitute an emergency and provided special flexibility under TRIPS rules
- Countries are free to permit “parallel importation” of medicine
- Countries may issue compulsory licenses
- Least developed members can disapply patents and data protection rules until January 1, 2016
Importance of Understanding the Rules

- Reduce the market exclusion power of pharmaceutical patent holders
- Minimize efforts of patent holders to persuade or prevent governments from taking advantage of TRIPS agreement flexibilities
- For procurement specialists to understand what is permitted, and/or seek expert guidance from relevant experts
Features of the International IPRs System

- Patents are granted on country-to-country or regional basis
- A medicine may be “on-patent” in some countries and “off-patent” (or generic) in others
- The patent situation in the exporting country may determine whether “generic” alternatives are available
- The patent situation in the importing country determines what steps are needed to authorize importation and distribution
Generic Alternatives

- A medicine under patent in Country A may be available off-patent in country B at a much lower price
- Some countries, such as India, only started to grant pharmaceutical product patents in 2005
- Originators have not secured patents in many countries
- LDC do not have to enforce patents
- Quality must be maintained and assured
Can your country procure and import generics?

- Yes, depending on the country and its patent situation – administrative steps may be required
- “Least developed” given special flexibility by WTO
- “Developing” may take advantage of TRIPS Agreement built-in flexibilities
- Whether a country developed or developing is a matter of self-selection – there is no WTO formal list
Least Developed Countries

Least developed counties enjoy maximum flexibility

- May elect *not to enforce* patents and/or data protection at least until January 1, 2016
- Thus, government has a “free hand” from standpoint of international obligations
- Government should take appropriate steps within national legal framework to “disapply” patents
- Executive or parliament may, for example, delegate decision to Health Minister or procurement authority
Developing Country

- Situation for developing countries more complicated than for least developed

- If a medicine is not under patent “in-country”, there is no patent barrier to producing locally or importing

  - If a medicine is under patent “in country”, then government may issue a “government use” authorization or “compulsory license”, and/or authorize “parallel importation”

- Voluntary license from patent holder

- Price Negotiations
Government Use (1)

- TRIPS Agreement permits granting of “compulsory” or “government use” licenses
- National patent law typically provides that the government (and third parties acting on its behalf) may use private patents. A “government use” license may authorize importation or local production without the consent of the patent holder
- The procedural requirements for government use licensing are normally much less burdensome than for compulsory licenses requested by private parties. U.S. patent law authorizes the government or its contractors to use any patent without notice to the patent holder
Government Use (2)

- Prior negotiations with the patent holder are not required when addressing urgent situations such as HIV/AIDS or for public non-commercial use.

- Adequate remuneration in the circumstances of the case must be paid to the patent holder, but this may be determined after-the-fact.

- The remuneration level may take into account the public health budget and the severity of the problem.

- Private enterprises may apply for compulsory licenses, and procurement authorities may purchase from them.

- Procurement authority would ordinarily for itself rely on a government use license.
Conditions of Compulsory licensing/government use (to safeguard the legitimate interests of the patent holder).
- granted on individual merits
- non assignable
- limited duration and for purposes for which granted
- termination on seizure of circumstances and unlikelihood or recurrence
- predominantly for supply of domestic market
- legal validity of authorization to use and remuneration are subject to judicial review, etc.
Parallel Importation

- Pharmaceutical companies often hold patents on the same medicine in many countries, and these are referred to as “parallel” patents.

- A country may decide to follow “international exhaustion” of patent rights. If so, the patent holder cannot block the importation of the medicine after it is lawfully first sold in ANY country.

- The procurement authority may look for the lowest price patented medicine on the world market for “parallel import”
Differential Pricing

- A patent-holder company may offer to sell ARVs or other medicines to a developing or least developed country at a discount to its developed country price(s), provided there is a contractual commitment not to re-export the lower-priced medicines.

- A commitment not to export in these circumstances is reasonable.

- Procurement authority should be careful to put in place adequate control mechanisms to meet its commitments.

- Developed countries may elect to block parallel imports to prevent low-priced medicines from entering their markets. This should not affect imports into developing countries.
Example from Lesotho (LDC)

OFFICE OF THE MINISTER
MINISTRY OF HEALTH
& SOCIAL WELFARE
P.O. BOX 514
MASERU 100
LESOTHO

02 August 2004

IDA FOUNDATION
PROCUREMENT SERVICES B.V.
AMSTERDAM
THE NETHERLANDS

ATTENTION: MACHIEL WIEDSMA

Dear Sir,

RE: PROCUREMENT OF ANTIRETROVIRALS IN LESOTHO

The Minister of Health of Lesotho has carefully considered the WTO documentation, being the TRIPS Agreement and DOHA declaration. Regarding the patent situation of antiretroviral drugs and the procurement therefore within the framework of the Global Fund against AIDS, Tuberculosis and Malaria and the UNDP, Lesotho hereby notifies you that:

Lesotho as an LDC and member of WTO declares an emergency situation with regards to HIV/AIDS. Therefore generic registered antiretroviral drugs may be imported into Lesotho following the aforementioned declarations. The aforesaid drugs will be used to treat people with HIV/AIDS without any commercial purpose. The Minister of Health hereby suggests that measures be taken to speed up supply of the aforesaid medical drugs in order to continue a comprehensive treatment AIDS Program in Lesotho.

I thank you,

Yours sincerely

[Signature]

DR M. PHOOKO
MINISTER OF HEALTH
LESOTHO
The Minister of Justice, Legal and Parliamentary Affairs, in terms of section 34 as read with section 35 of the Patents Act [Chapter 26:03], hereby makes the following notice:—

1. This notice may be cited as the Declaration of Period of Emergency on (HIV/AIDS), Notice, 2003.

2. The Minister hereby declares an emergency for a period of five years with effect from 1st January, 2003 to 31st December, 2008 for the purpose of enabling the State or a person authorised in writing by the Minister under section 34 of the Act—

(a) to make or use any patented drug, including any antiretroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions;

(b) to import generic drugs used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.
Role of Procurement Authorities

- Should evaluate national IPRs situation and determine whether changes are necessary to take advantage of TRIPS Agreement flexibilities
- Act as advocates among government agencies, some of which may have different priorities
- Monitor the patent and registration situation. This situation will directly affect procurement options
- When questions arise, do not hesitate to seek guidance from patent specialists in your country
Are ARVs Patented in Country A?

- Even though ARVs may be off-patent in A, they may be under patent in Country B. Patents are granted on country-by-country basis.

- MSF maintains a list of the ARVs under patent in a number of countries, including Country A. Ten ARVs were found to be patented in Country A, several of which are on Country A’s standard HIV-AIDS treatment list.
Resources for more information

- Pricing: Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS – UNICEF, UNAIDS, WHO, MSF – http://www.who.int/medicines (and others)
Resources (cont..)

For details on the WTO TRIPS Agreement:


For details on how the TRIPS Agreement and intellectual property rules affect medicines procurement:

- Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO, 5 J. Int’l Econ. L. 469 (Oxford)
- Carlos Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement (South Centre 2002).
- Carlos Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries, South Centre (2000)
Resources (Cont.)

- **Drug Patents Under the Spotlight** – MSF – [http://www.accessmed-msf.org](http://www.accessmed-msf.org)

For pricing of ARVs


For guidance on the Decision on Implementation of Paragraph 6 of the Doha Declaration

- **World Bank Model Notifications and Legislation (with commentary)**