IP and Health in Developing Economies:
Setting the Policy Context

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Dr Socorro Escalante
WHO Country Office for Viet Nam

Presentation Outline

1. TRIPS: Principles and relevance to public health
2. TRIPS and access to medicines
3. How do countries fare? Good practices and challenges
4. Setting the Policy Context: Global and Local

TRIPS: Principles and Relevance to Public Health

TRIPS: Basic Principles

Basic Mandate:

- Minimum standards for the protection and enforcement of intellectual property rights

Objectives:

1. Promotion of technological innovation
2. Transfer and dissemination of technology

- Mutual advantage of producers and users
- Conducive to social and economic welfare
- Balance of rights and obligations

TRIPS: Basic Principles

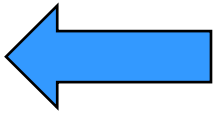
Principles relevant to public health

…consistent with the provision of the agreement, Members may:

1. Protect public health and nutrition and promote public health interest
2. Prevent abuse which unreasonably restrain trade and transfer of technology
3. Provide exceptions, exclusions and limitations to rights in: national emergencies, public-non commercial use, anticompetitive practices

TRIPS: Basic Principles

Provisions relevant to public health

1. Patents 
2. Trademarks including service marks
3. Undisclosed information

TRIPS and Access to Medicines

TRIPS and Access to Medicines

Why access to Medicines?

In the context of health and development

- Medicines save lives, prevent and treat diseases and contribute to the over-all achievement of quality of life
- Access to medicines is a part of the fulfilment of the right to health

TRIPS and Access to Medicines

Why access to Medicines?

In the context of trade

- Medicines are public health goods
- Trade in medicines defies the laws of supply and demand and basic market forces
- Medicines are priced as high as the market can bear

TRIPS and Access to Medicines

Why access to Medicines?

In the context of trade

- Trade in medicines is founded on “brand loyalties” and complicated by information asymmetries

Cartoon by April Girouard

TRIPS and Access to Medicines

The World's Medicines Situation

- Global pharmaceutical market value: $975 billion by 2013 *(IMS Health,2010)*
- Yet inequalities to access exist
- At least 1/3 of the world's population has no access to Medicines (WMS, 2011)
- The poor bears the burden of inequality

TRIPS and Access to Medicines

The World's Medicines Situation

Availability

- Public sector availability of low priced generic medicines is less than 60% across WHO Regions
- Range: 32% in Eastern Mediterranean to 58 % in Euro
- Over-all availability: Less than 60% in Western Pacific, South-East Asia and Africa

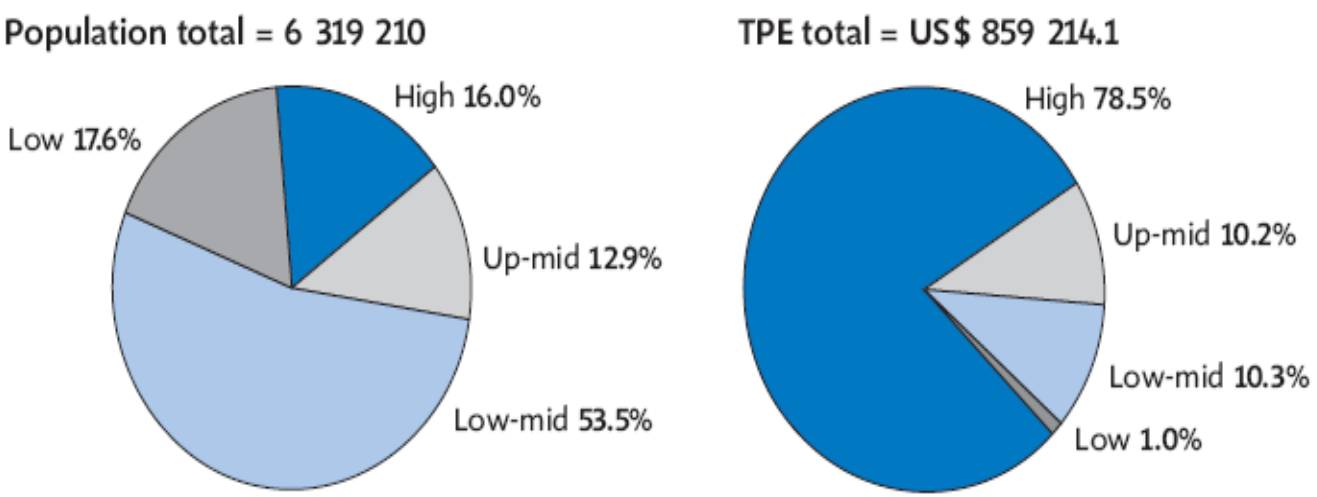
Source: World Medicines Situation, WHO, 2011

TRIPS and Access to Medicines

The World's Medicines Situation

Expenditure

Distribution of world population and total pharmaceutical expenditure (TPE) among countries grouped by income level, 2006

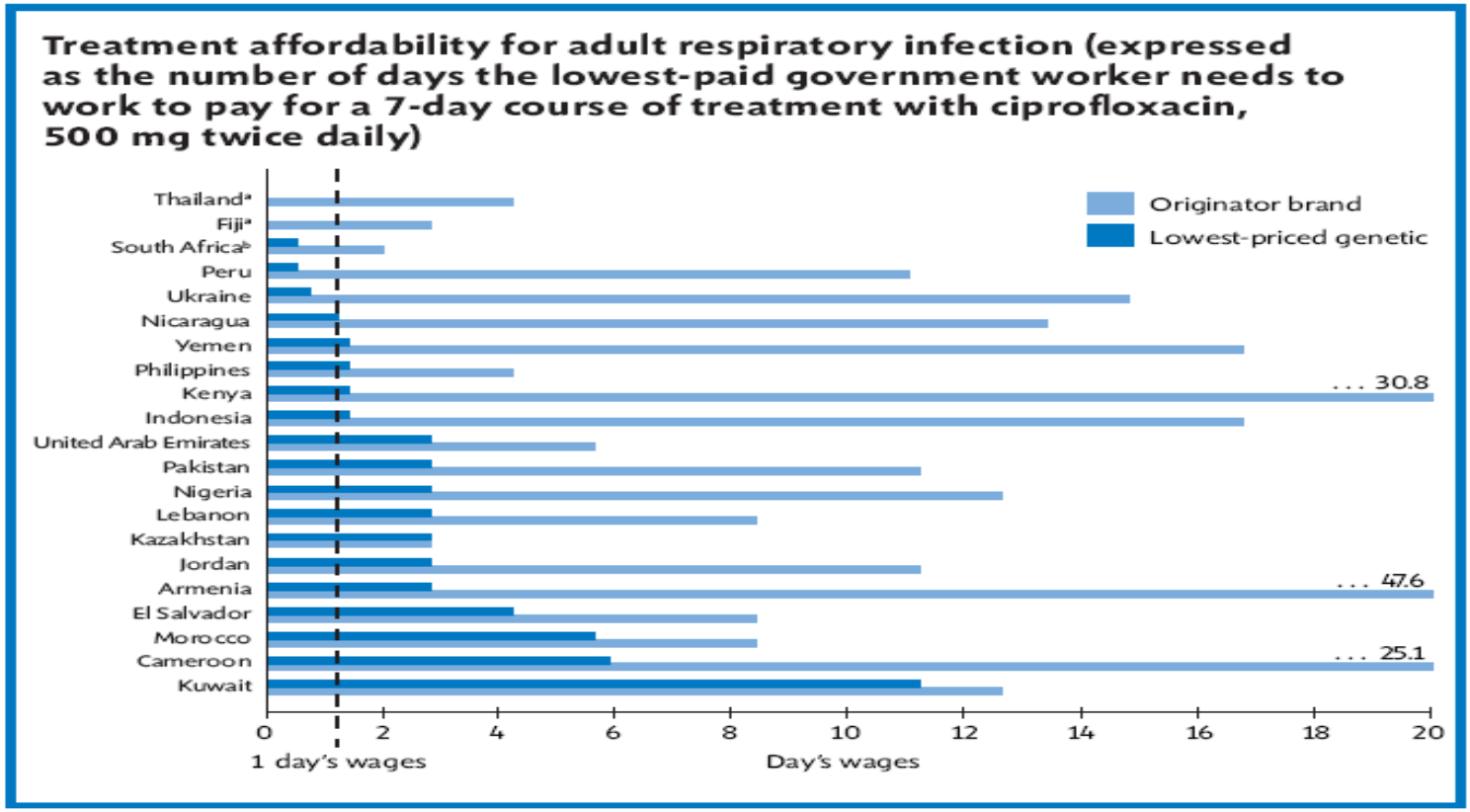


Source: WHO NHA database

TRIPS and Access to Medicines

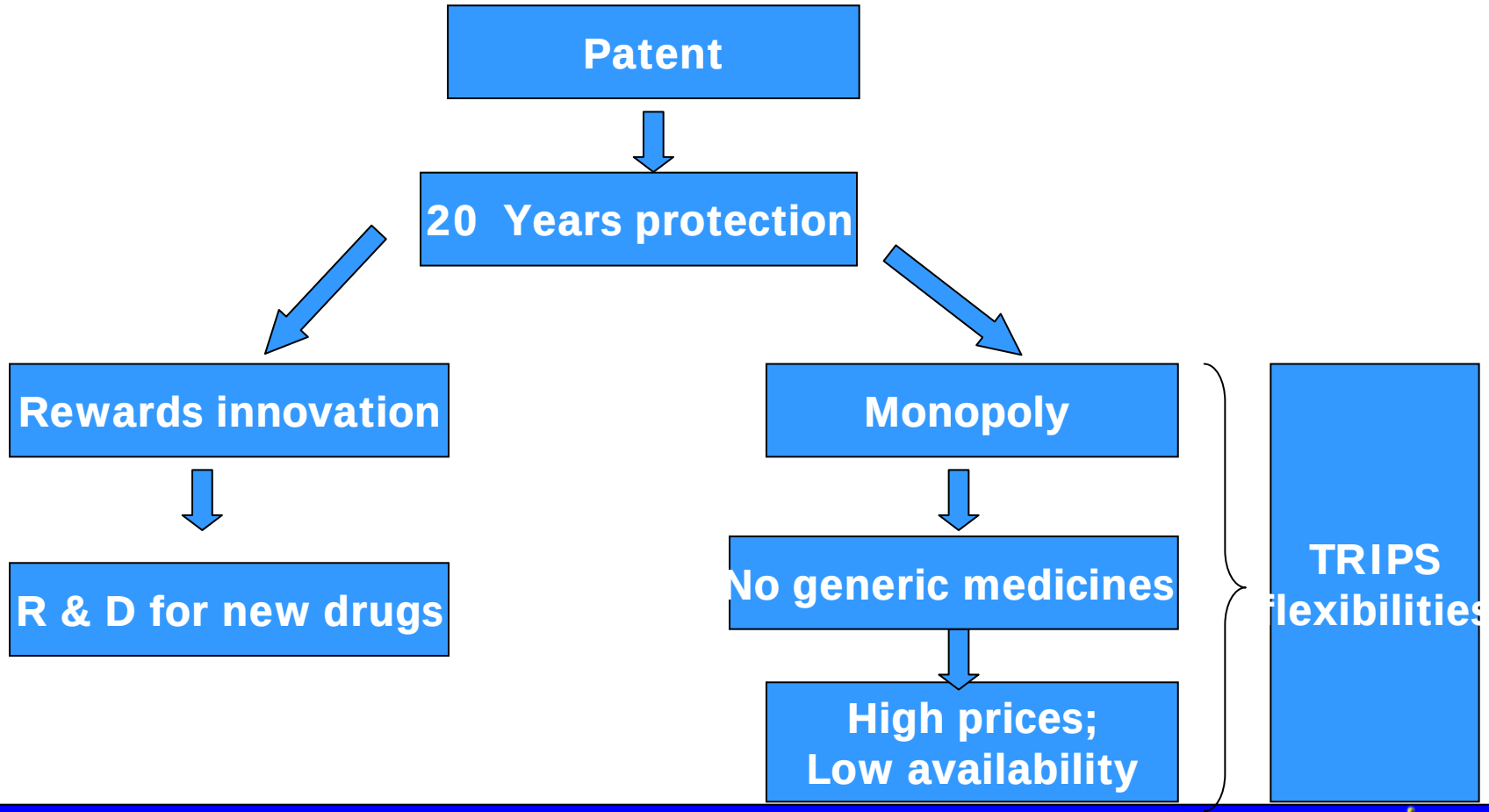
The World's Medicines Situation

Prices and affordability



TRIPS and Access to Medicines

The Role of TRIPS



TRIPS and access to Medicines

The Role of TRIPS: TRIPS Flexibilities

Types of Flexibilities	Examples
Preventative: *Policy options to ensure that patents do not hinder access to affordable medicines. Advantages: easier, faster, less politically sensitive compared to some remedial measures.*	**Exclusion from Patentability:** Exclude new use of known substances, methods and processes **(Articles 27.2 and 27.3)** **Patentability Criteria:** Develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and "evergreening" opportunities. **(Articles 1 and 27.1).** **Patent Opposition:** Allow pre-grant and post-grant **patent opposition** in fast, accessible and cost-efficient manner. **Waiver for LDCs:** LDCs should utilize the waiver to provide patent protection for pharmaceuticals until 1 January 2016 (and possibly longer, if extended).[49]

Source: Good Practice Guide, TRIPS Flexibilities, UNDP, 2010

TRIPS and access to Medicines

The Role of TRIPS: TRIPS Flexibilities

Remedial:

Preventative flexibilities cannot always be used to meet existing and emerging needs to secure access to affordable medicines. Therefore, series of remedial flexibilities are included in the TRIPS Agreement.

Compulsory Licenses and Government Use Orders (Article 31 (a)—(j))

Compulsory Licenses for Export under the **WTO 30 August, 2003 Decision.**

Exceptions: Bolar (early working) exception, research and experimental use exception, individual use **(Article 30)**

Use of **National Competition Laws** to prevent IPR abuse and provide remedies **(Articles 8.2, 31(k) and 40)**

Parallel Importation (Article 6)

Source: Good Practice Guide, TRIPS Flexibilities, UNDP, 2010

TRIPS and access to Medicines

The Role of TRIPS: TRIPS Flexibilities

Enforcement:

Related to obligations under Part III of the TRIPS Agreement, which sets minimum standards for IPR enforcement.

No border measures for suspected patent infringement **(Article 51)**

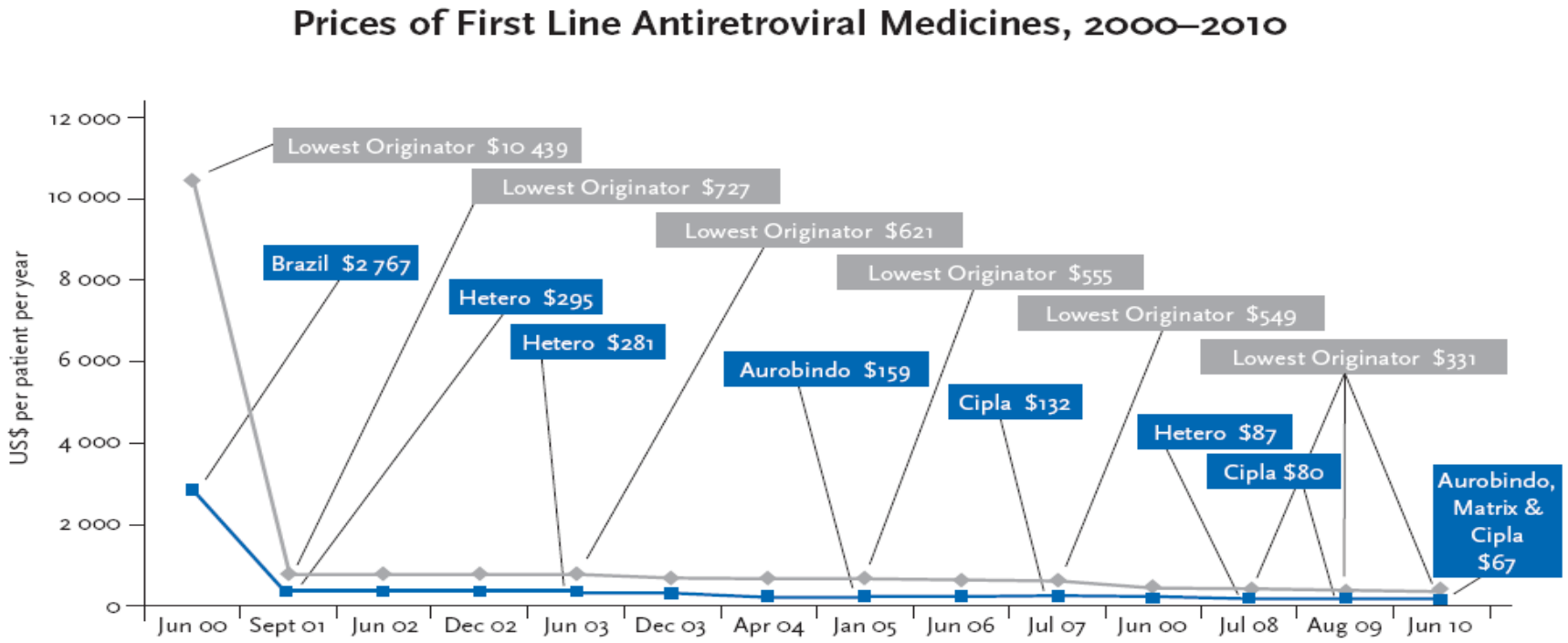
No criminalization of patent infringement **(Part III, Section 5)**

Source: Good Practice Guide, TRIPS Flexibilities, UNDP, 2010

TRIPS and access to Medicines:

Are patents barriers to access?

Price and monopolies



Source: MSF (2010), *Untangling the Web of Antiretroviral Price Reductions*, 13th ed.

TRIPS and access to Medicines:

Are patents barriers to access?

TRIPS-plus provisions that restrict registration of affordable generic drugs

- Data Exclusivity
- Patent linkaging
- Waiving the LDC exceptions
- Broadening patentability
- Extending patent terms
- Restricting oppositions

TRIPS and access to Medicines:

Are patents barriers to access?
Complications to local pharmaceutical production

Local production of generic medicines and vaccines face complicated patent landscapes:

Examples:

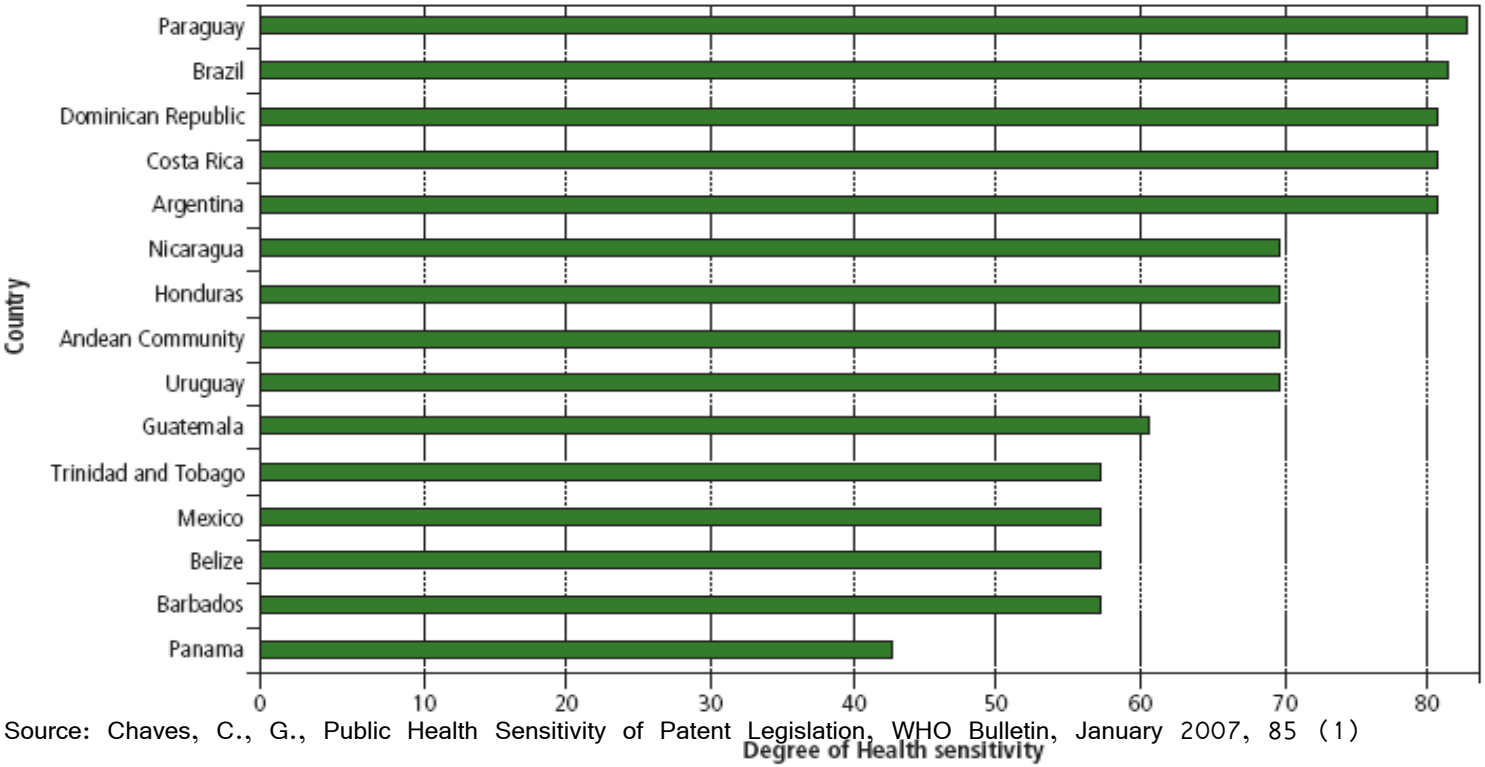
1. At least 81 US patents for human pailloma virus vaccines have been granted (Morgan 2010)
2. Malaria: 167 patent families filed by 75 different organizations (Shotwell, 2007)
3. Thailand: preponderance of patents in the pharmaceutical category: 51% related to drugs, vaccines and biomaterial products, 85% of patents for biotechnology products were foreign owned (Changthavorn and Chanvarasuth, 2010)

How do Countries Fare: Good practices and challenges

How do countries fare?

Variable capacity for both legal adoption and implementation

Fig. Health sensitivity of patent legislation in selected countries, 1996-2005



Source: Chaves, C., G., Public Health Sensitivity of Patent Legislation, WHO Bulletin, January 2007, 85 (1)

How do countries fare?

Good Practices: Application of TRIPS Flexibilities

Compulsory licensing:

- Used by governments for domestic production or import of ARV's and other essential medicines
- Further strengthen by the 30 August 2003 Decision on **Paragraph 6**
- Allowed countries with no production capacity to import medicines subjected to Compulsory License

Summary Table: Examples of compulsory licenses by/for developing countries[1]

Date	*Country*	*Type*	*Product*	*Duration*	*Royalties*
April 2003	Zimbabwe	CL	all HIV/AIDS-related medicines	not indicated	not indicated
Oct. 2003	Malaysia	GU	- didanosine - zidovudine - FDC didanosine+zidovudine	2 years	not indicated
Sept. 2004	Zambia	CL	FDC of lamivudine+ stavudine+nevirapine	until notification of expiry of the compulsory licence	2.5%
Oct. 2004	Indonesia	GU	- lamivudine - nevirapine	7-8 years (remaining patent term)	0.5%
Nov. 2006	Thailand	GU	efavirenz	until 31 December 2011	0.5%
Jan. 2007	Thailand	GU	lopinavir/ritonavir	until 31 January 2012	0.5%
Jan. 2007	Thailand	GU	clopidogrel	patent expiry or no longer needed	0.5%
March 2007	Indonesia	GU	efavirenz	until 07 August 2013	0.5%
May 2007	Brazil	GU	efavirenz	5 years	1.5%
Sept. 2007	Canada for export to Rwanda	CL	FDC of lamivudine+ zidovudine+nevirapine	2 years	2%
Jan. 2008	Thailand	GU	several cancer drugs	patent expiry or no longer needed	3-5%

CL = compulsory license; GU = government use (CL for public non-commercial use).

How do countries fare?

Good Practices: Application of TRIPS Flexibilities

Compulsory licensing, 30 August 2003 Decision

Country Example: Rwanda

- The first WTO Member to use the provision (2007)
- Importation of Apo-TriAvir, a generic version of ARV triple combination patented by GSK, Shire and Boehringer Ingelheim
- Canada in 2007 issued compulsory license to local generic manufacturer Apotex to produce 15.6M tablets for export to Rwanda over the next 2 years.
- Products were shipped in September 2008

How do countries fare?

Good Practices: Application of TRIPS Flexibilities

Public non-commercial use of patents (Government Use)

- The right of the State to use a patent without the consent of the patent holder for public health purposes (Art 31)
- Waiver on the requirement of prior negotiations

Country Examples: Zimbabwe

- Sections 34 and 35 of the Patent Act: authorize the use of patented inventions for the service of the state
- In 2003, granted authority to Varichem to produce ARV's

How do countries fare?

Good Practices: Application of TRIPS Flexibilities

Parallel Importation

- Import and resale in a country without the consent of the patent holder

Country Examples: Kenya and Philippines

- Adopts the international exhaustion principle in its Intellectual Property Act of 2001
- Philippines parallel importation of drugs for use in public health sector

How do countries fare?

Good Practices: Application of TRIPs flexibilities:

Transition Period:

- Least developed countries (LDC's) were given extension as to when to implement TRIPs agreement *(Art 66.1)*
- For pharmaceutical patents: extended up to January 2016 (Doha Declaration)

Country Example: Cambodia

- Patent legislation enacted in 2004
- Specific provision that the patent law has no effect on pharmaceuticals until January 2016 (Cambodian Law on Patent, Art 136)

How do countries fare?

Challenges: Dealing with TRIPs-plus provisions:

- Data exclusivity and patent linkaging are the most common
- Foreign and bilateral trade agreements continue to exert pressure in developing countries

Country example: Viet Nam

- Provisions on data exclusivity and patent linkaging in the circular for medicines registration

Setting the Policy Context: Global and Local

Setting the policy context

Intellectual property rights should be taken and applied under the global public health principle on access to medicines

Setting the policy context: Global

1. Access to Medicines as a part of the fulfilment of the right to health

ICESCR General Comment 3: states that the right to medical services in Article 12.2 (d) of the ICESCR includes the provision of essential drugs “as defined by the WHO Action Programme on Essential Drugs”(12).

Setting the policy context: Global

2. MDG 8

Target 8.E:

In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries

Setting the policy context: Global

3. WTO Legal Framework on IP on the context of the Members rights to promote public health and access to medicines:

a. TRIPS Agreement

b. DOHA Declaration

c. WTO Decision on Paragraph 6

Setting the policy context: Local

1. Adopting the human-rights based approach for access to essential medicines
2. Trade and Policy coherence: Upholding the DOHA Declaration
3. Use of TRIPs flexibilities: Enacting enabling laws to enable countries to make use of data exclusivity

Setting the policy context: Local

Supportive policies and actions:

- Actions on foreign and/or bilateral trade agreements
- Understanding of impact of TRIPs-plus provisions on access to essential medicines
- Wider involvement on negotiations: from trade to health participation

Setting the policy context: Local

Supportive actions:

2. Local production: fostering research and innovation

- Roadmaps for research and innovation
- Models and mechanisms for transfer of technology

Setting the policy context: Local

Supportive actions:

3. Building national capacity

- Establishing structures and mechanisms for application of TRIPS flexibilities
- Improving internal technical capacity

Thank you