



# Topic 2: Patent-related Flexibilities in Multilateral Treaties and Their Importance for Developing Countries and LDCs

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# Overview

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- Introduction
- TRIPS Agreement
- Patent Related Flexibilities
  - Defining
  - Key Patent-related Flexibilities
  - Research Exemption
  - Compulsory Licences
  - Constraints
- Concluding Remarks

# Introduction

## Changing Faces of Africa: *New Challenges and Opportunities*



Urbanization growth: 41%  
(2000-09)  
Highest in the world

Growing youth population: impact  
lifestyle & commerce.



Economically active population:  
70.7%  
Highest in the world



Literacy growth: 8.5%  
(2000 -09)  
Second Highest in the world

**Changing demographics creating  
new challenges and opportunities**

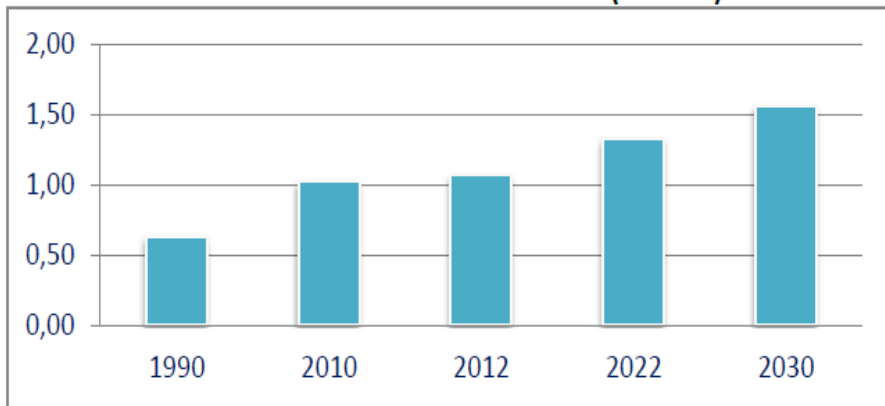


Fastest Growing  
mobile penetration

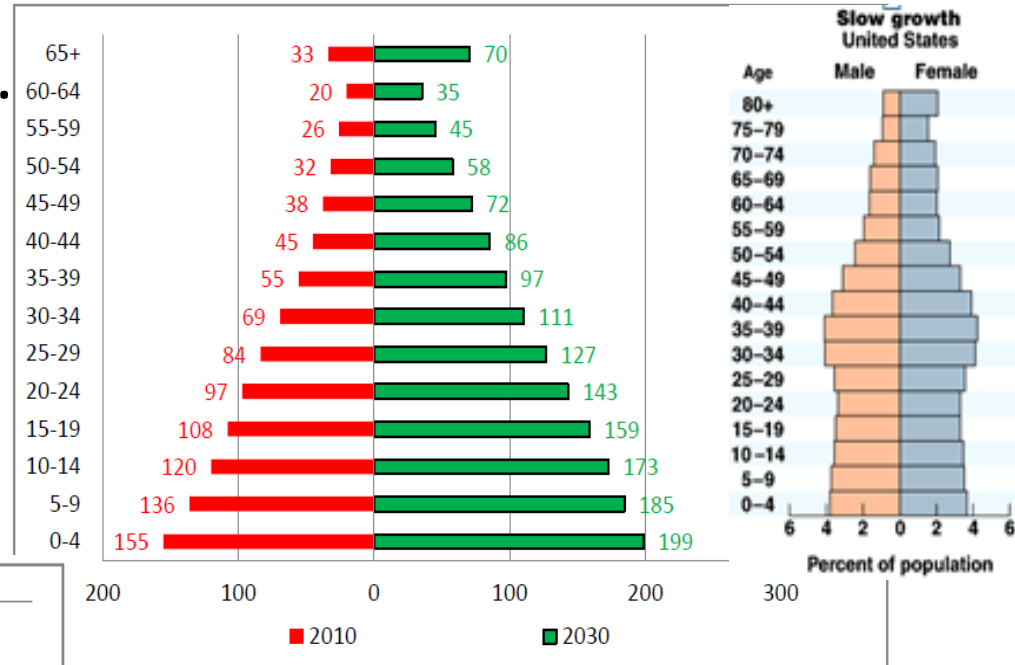
# Introduction

## Socio-economic Trends: *Youthful Population*

**Growing youth population impacting lifestyle and commerce.**



Source: AfDB based on UN Population Division data.



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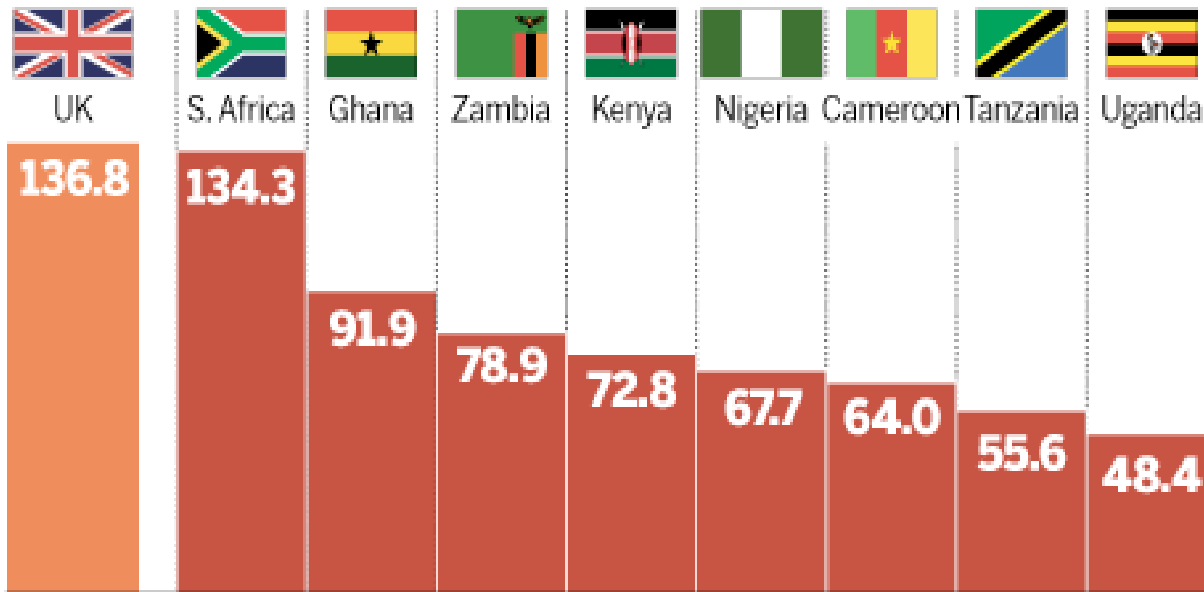
**Economically active population: 70.7% Highest in the world**

# Introduction

## Socio-Economic Trends: *Mobile Connectivity*

### Sub-Saharan Africa's mobile opportunity

Mobile subscribers penetration rate, end 2012 (%)



Source: Strategy Analytics

Figures can be more than 100% due to a person having more than one mobile

### Opportunity for mobile to be a game changer:

- Enterprise level
- BOP applications
- Service Delivery

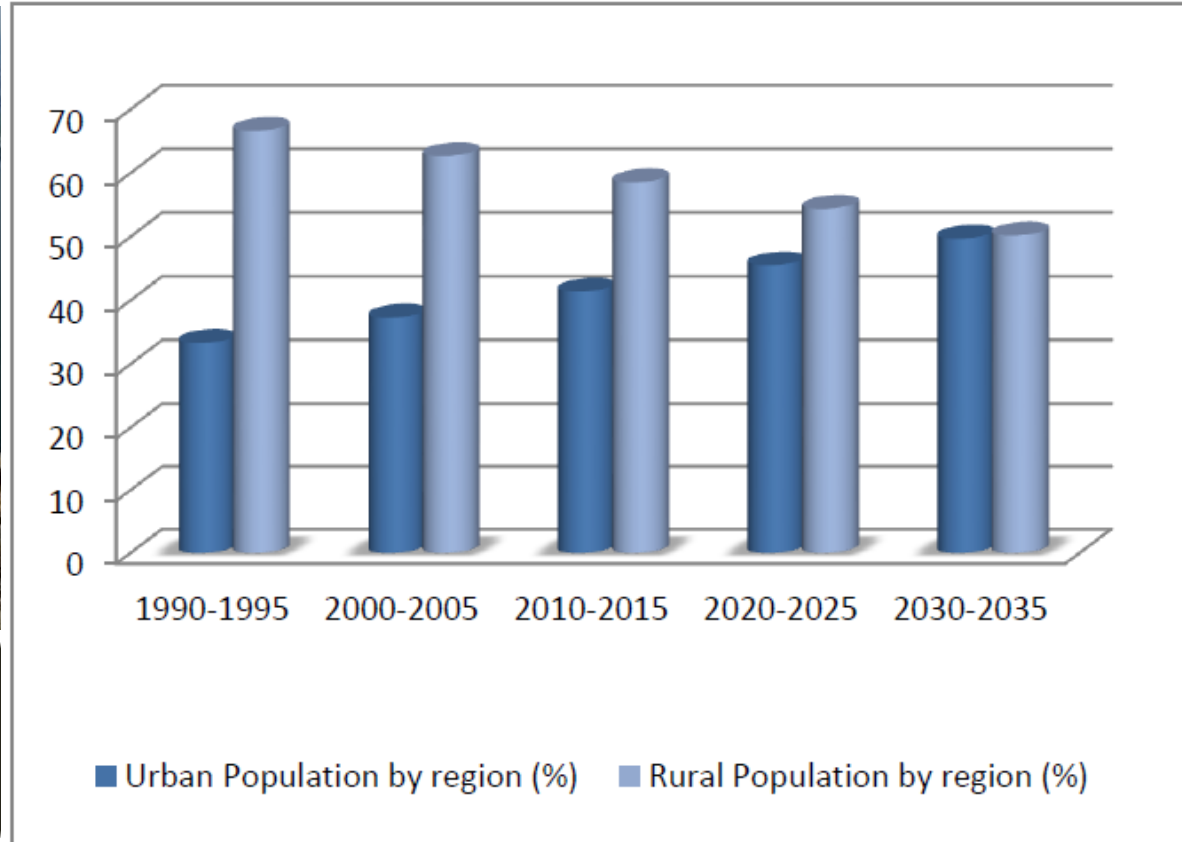


# Introduction

## Socio-Economic Trends: *Urbanisation*



**Urbanization growth: 41%  
(2000-09)  
Highest in the world**



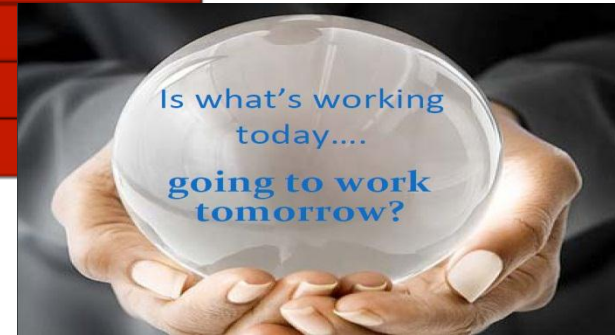
Source: AfDB based on UN Population Division data.

# Introduction

## World's Fastest Growing Economies

Worlds 10 fastest-growing economies, annual average GDP growth (%)			
<u>Country</u>	<u>2001 – 2010</u>	<u>Country</u>	<u>2011 - 2015</u>
Angola	11.1	China	9.5
China	10.5	India	8.2
Myanmar	10.3	Ethiopia	8.1
Nigeria	8.9	Mozambique	7.7
Ethiopia	8.4	Tanzania	7.2
Kazakhstan	8.2	Vietnam	7.2
Chad	7.9	Congo	7.0
Mozambique	7.9	Ghana	7.0
Cambodia	7.7	Zambia	6.9
Rwanda	7.6	Nigeria	6.8

Source: Economist, IMF, January 2011

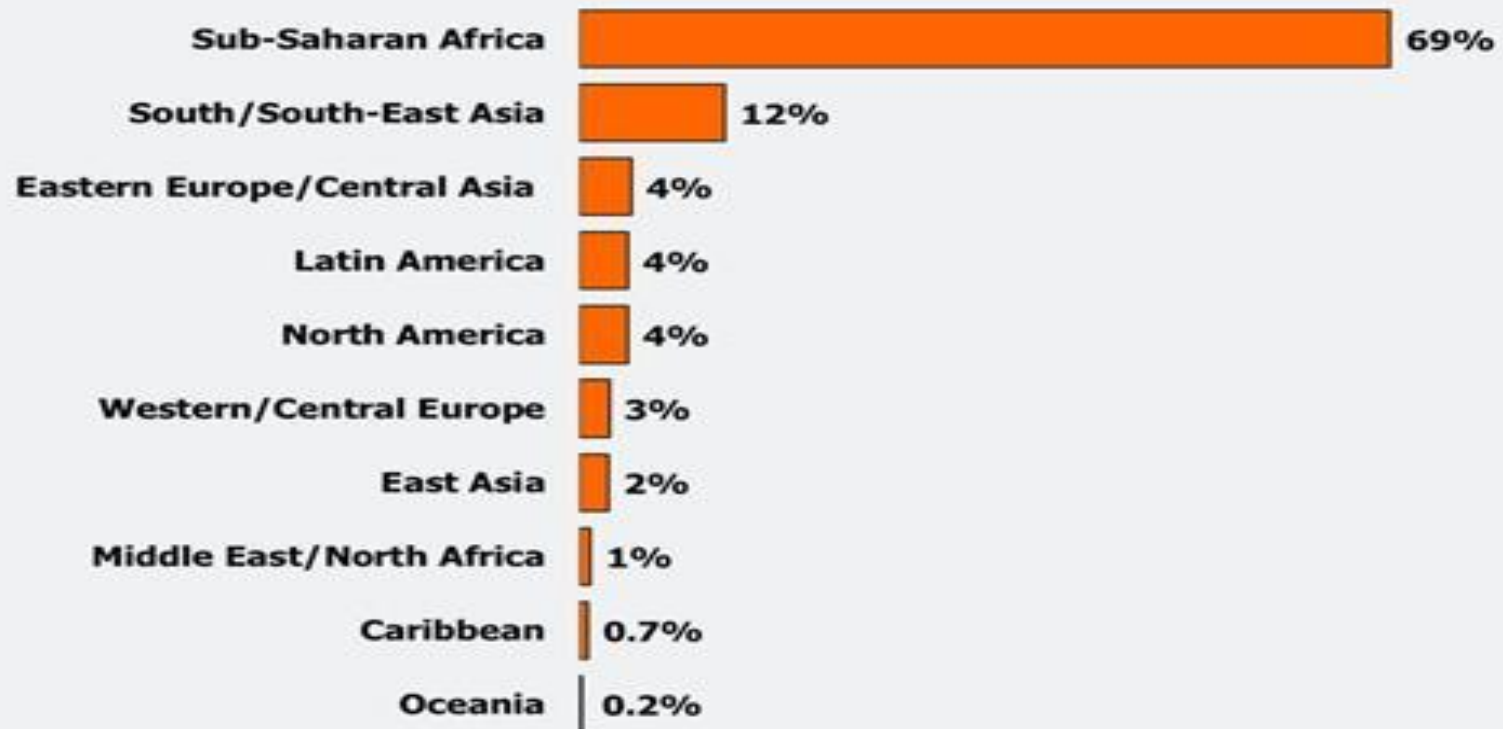


**Is it Sustainable?**

# Introduction

## Health Challenges Facing Africa

### People Living with HIV by Region, as Percent of Global Total, 2011



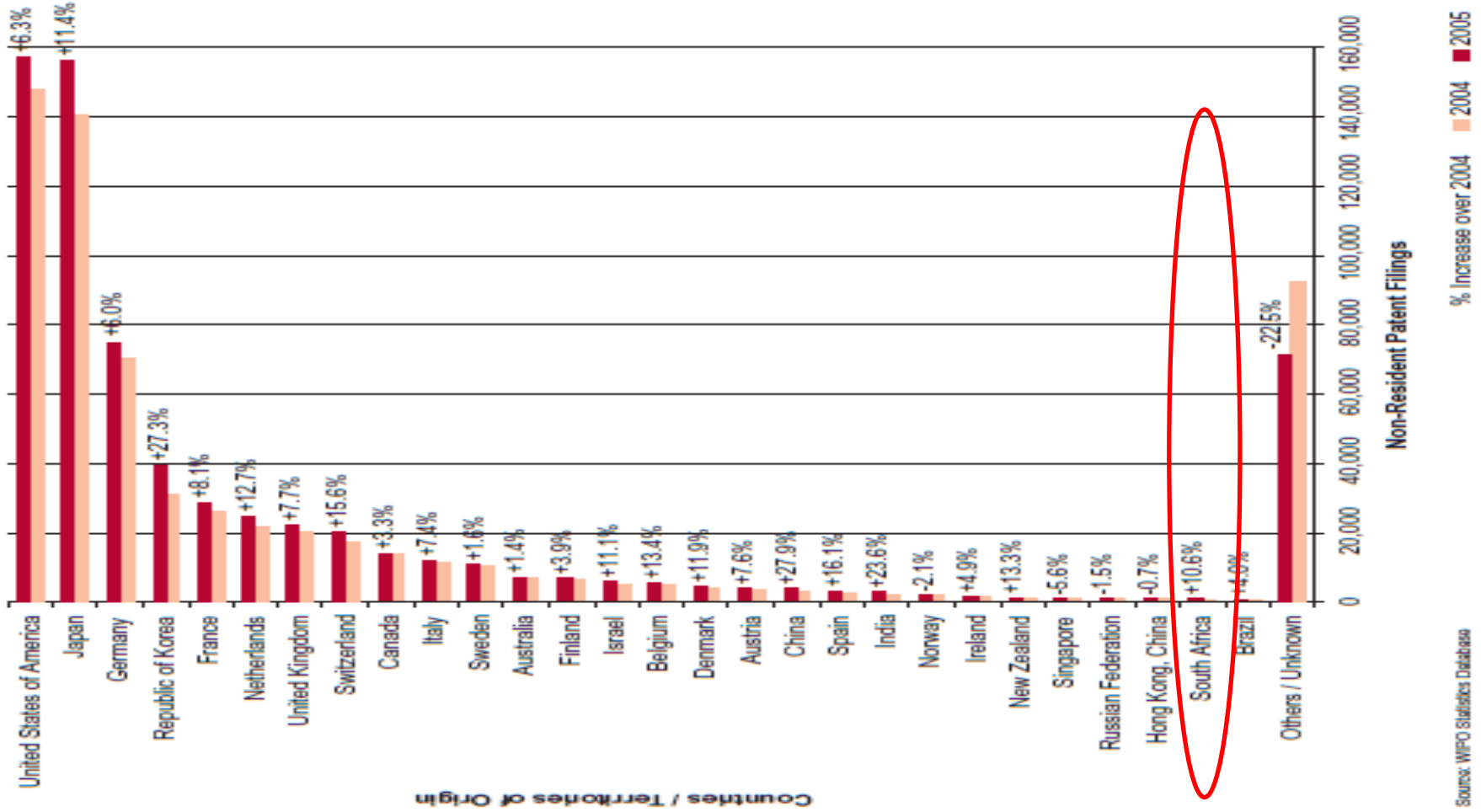
SOURCE: Kaiser Family Foundation, based on UNAIDS, *Report on the Global AIDS Epidemic*, 2012.





# Introduction

## Africa's Low Technological Innovation Base



# TRIPS AGREEMENT

## Objectives

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### □ *Article 7: Objectives*

- **IPR protection and enforcement** should **contribute** to the **promotion of technological innovation** and to the **transfer and dissemination of technology**
- to the **mutual advantage of producers and users** of technological knowledge
- in a **manner conducive to social and economic welfare**, and to a **balance of rights and obligations**.

# TRIPS AGREEMENT

## Principles – Article 8

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1. Members may, in formulating or amending their laws and regulations, **adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development**, provided that **such measures are consistent with the provisions of this Agreement.**
2. **Appropriate measures**, provided that they are **consistent with the provisions of this Agreement**, may be needed to **prevent the abuse of intellectual property rights by right holders** or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

# TRIPS AGREEMENT

## Basis of Flexibilities

- “In view of the **special needs and requirements of least-developed country Members**, their **economic, financial and administrative constraints**, and their **need for flexibility to create a viable technological base .....**”

### Article 30 (TRIPS Agreement)

- **Members can establish limited exceptions to the exclusive rights conferred by a patent**

### Cumulative 3-part test to comply with Art. 30

- **Limited exception**
- **Not unreasonably conflict with normal exploitation**
- **Not unreasonably prejudice the legitimate interests of the patent owner**

# FLEXIBILITIES

## Defining Flexibilities

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### □ Flexibilities

*“there are **different options** through which **TRIPS obligations** can be transposed into national law so that **national interests** are accommodated and yet **TRIPS provisions and principles** are complied with.”* CDIP/5/4 Rev

### □ Categories / Grouping of Flexibilities:

- Based on the point in time at which Members may resort to them:
  - i) in the **process of the acquisition of the right**
  - (ii) **defining the scope of the right**
  - (iii) when **enforcing the right**

# FLEXIBILITIES

## Key Patent Flexibilities / Exceptions

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- ❑ **Flexibilities in the process of acquisition of the right**
  - Disclosure Related Flexibilities
  - Examination of Patent Applications
  - Patentability of Substances Existing in Nature
  
- ❑ **Flexibilities in defining the scope of the right**
  - Research exemption
  - Regulatory review exemption
  - Compulsory licensing and Government Use
  - Exhaustion of rights/Parallel Importation
  
- ❑ **Flexibilities when enforcing the right**
  - Ex-officio IP Office Control of Contractual Anti-competitive clauses

# FLEXIBILITIES

## Research Exemption

- ❑ *Canada-Patent Protection of Pharmaceutical Product* case (DS114), defines the research exemption as:
  - the exception under which **use of the patented product for scientific experimentation**, during the term of the patent and without consent, **is not an infringement**”.
- ❑ Rationale:
  - *“... exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a ‘legitimate interest’ in using the patent disclosure to support the advance of science and technology.”*

# FLEXIBILITIES

## Compulsory Licensing

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- ❑ An instrument to prevent abuses of the exclusivity and ensure wider application of patented subject matter
- ❑ **Safeguards for governments** to ensure public interest objectives, including national security, **public health** and **to respond to national emergencies**
- ❑ Ensure **fair exercise of patent rights** - encourage voluntary licenses at reasonable conditions
- ❑ Mechanism of **inducing competition**
- ❑ Seen as a tool to improve access to patented products / HIV drugs at reasonable prices within region



# FLEXIBILITIES

## Compulsory Licensing – Legislative Provisions

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- ❑ Entitle the government, or a third party who is authorized by the government, to **use the patented invention without authorization of the patentee** under **certain circumstances of public interest**:
  - national security
  - nutrition
  - **health** or the development of other vital sectors of the national economy
  - **remedies a patentee's anti-competitive practice**

# FLEXIBILITIES

## Compulsory Licensing – Scope of Legislative Provisions in National Laws, *Examples*

COUNTRY	PROVISION OF LAW	COMPULSORY LICENSING FOR NON-WORKING OF THE PATENT	COMPULSORY LICENSING FOR DEPENDENT PATENT	COMPULSORY LICENSE TO CORRECT PATENT ABUSE	COMPULSORY LICENSE FOR PUBLIC INTEREST	SEPARATE PROVISION ON GOVERNMENT USE
<b>Morocco</b>	Articles 25-39 of Law No. 17-97 Concerning Protection of Industrial Property (Implemented by Decree No. 2-00-368 of 07/06/2004)	Yes	Yes	Not explicitly provided	Yes	Yes
<b>Egypt</b>	Articles 23 and 24 of the Law No. 82 of 2002	Yes	Yes	Yes	Yes	Not explicitly provided
<b>Ethiopia</b>	Sections 29-33 of the Proclamation of the Industrial Property Law No. 123 of the 10/05/1995	Yes	Yes	Not explicitly provided	Not explicitly provided	Not explicitly provided
<b>Ghana</b>	Sections 45- 52 of the Patents Law No. 305A of 30/12/1992	Yes	Yes	Not explicitly provided	Yes	Not explicitly provided
<b>Kenya</b>	Sections 72- 78 and 80 of the Industrial Property Act No. 3 of 27/07/2001	Yes	Yes	Not explicitly provided	Not explicitly provided	Yes
<b>South Africa</b>	Sections 55-56 of the Patents Act No. 57 of 1978 as last amended by Act No. 58 of 2002	Yes	Yes	Yes	Not explicitly provided	Not explicitly provided

# FLEXIBILITIES

## Compulsory Licensing – Some Examples

### ZAMBIA

- September 21, 2004  
Zambian Minister of Domestic Trade and Consumer Affairs issued a compulsory license
- Patents for lamivudine, stavudine and nevirapine.
- CL granted to Pharco Ltd., a local producer, to produce a triple fixed-dose combination
- Maximum royalty rate of 2.5% to apply

### ZIMBABWE

- May 2002, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs declared a Period of Emergency in order to override antiretroviral drug patents for a period of 6 months
- Government use compulsory license to make, use or import generic HIV/AIDS medicines
- 2003, period of emergency extended by five years (to 31 December 2008)
- With assistance from India, Zimbabwe began local production of antiretrovirals through the generic company Varichem Pharmaceuticals (Private) Limited

# FLEXIBILITIES

## Compulsory Licensing – Some Examples

### ❑ SOUTH AFRICA

- *September 19, 2002* - Hazel Tau and TAC filed complaint with Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI)
- Excessive pricing regarding ritonavir, lamivudine, nevirapine and ritonavir+lamivudine

- **Commission ruling (*October 16, 2003*):**
  - GSK and BI contravened the Competition Act of 1998.
  - abused their dominant positions in their respective anti-retroviral (ARV) markets
  - engaged in restrictive practices:
    - 1. Denied a competitor access to an essential facility
    - 2. Excessive pricing
    - 3. Engaged in an exclusionary act

# FLEXIBILITIES

## Compulsory Licensing – Some Examples

- (December 10, 2003)
- GSK/Competition Commission settlement
- BI followed suit thereafter
- Settlement based on voluntary licence

### ○ GSK Settlement

- 1) Extend a voluntary licence granted to Aspen Pharmacare in October 2001 in respect of the public sector to include the private sector
- 2) Grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare
- 3) Permit licensees to export ARVs to sub-Saharan African countries
- 4) Permit importation of the drugs for distribution in South Africa if licensee does not have manufacturing capability in South Africa
- 5) Permit licensees to combine the relevant ARV with other antiretroviral medicines
- 6) Charge royalties of no more than 5% of the net sales

# FLEXIBILITIES

## Constraints

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- ❑ Domestic pharmaceutical manufacturing capacity
  - Reliance on importation which may not necessarily have desired price reduction and access
  - Need to build pharmaceutical research capability within the region
- ❑ Pressure against compulsory licences on basis of free trade
- ❑ Lack of awareness of patent system
  - **Exhaustion of rights:** Increased use of off-patent drugs
  - **Exhaustion of rights:** Territoriality of patents and in some cases, no patents in certain countries within region
  - Lack of technical capacity relating to negotiation / implementation of IP
- ❑ Technical capacity
- ❑ Bilateral agreements (e.g. AGOA) - need for caution

# CONCLUDING REMARKS

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- ❑ A number of countries have amended laws to include compulsory licence / government use
- ❑ Specific instances of use of compulsory licence / government use within region
- ❑ Use of flexibilities in the area of compulsory licences / government use, limited to public health or national emergencies
- ❑ In South Africa, voluntary licencing was fall back position, thereby preventing compulsory licensing

# Thank You!

## The Innovation Hub

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