



REPUBLIC OF SOUTH AFRICA



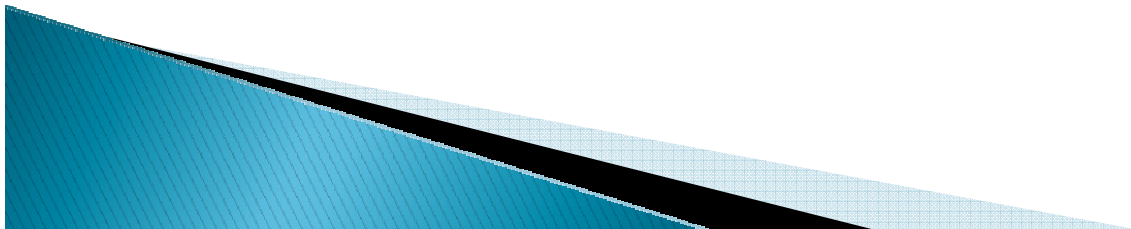
Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

Topic 10: The Use of Compulsory Licenses

**Durban, South Africa
January 29 to 31, 2013**

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

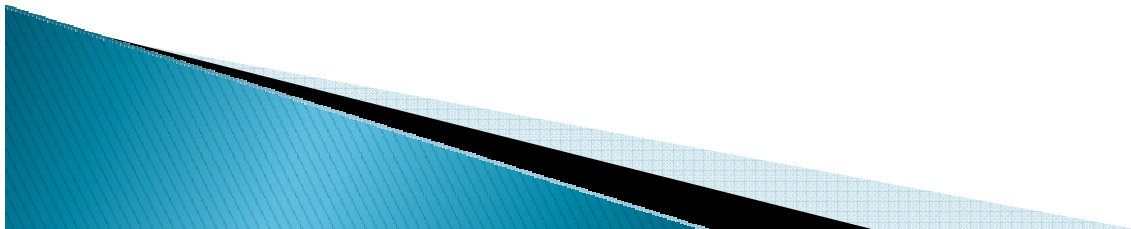
**Durban, South Africa, January 29 to
31, 2013**



TOPIC 10

- ▶ The use of compulsory licenses
- ▶ The experience of Zimbabwe

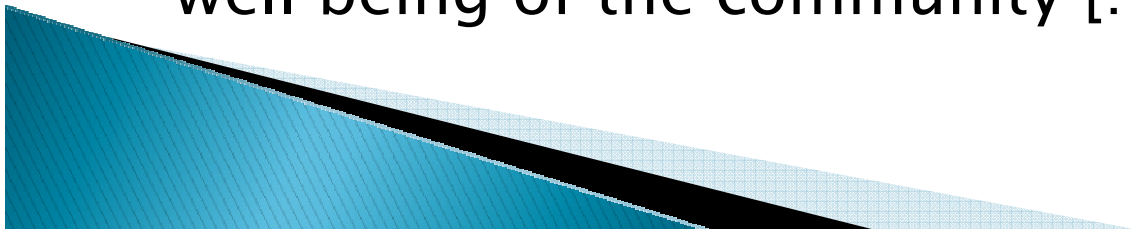
- ▶ Presenters
 - Mr. W. Mushayi (Deputy Registrar)
 - Mr. I. Mawire (Principal law officer)



Zimbabwe compulsory licensing

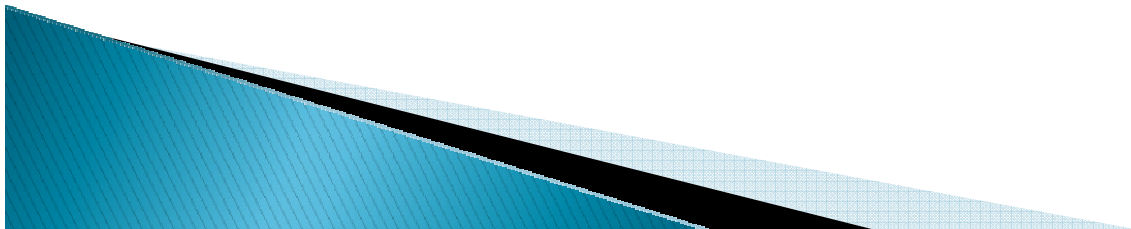
- ▶ According to Section 35(1) of Zimbabwean Patents Act:

35. (1) During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty- four shall include the power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient –for the maintenance of supplies and services essential to the life of the community; or for securing a sufficiency of supplies and services essential to the well-being of the community [...]"



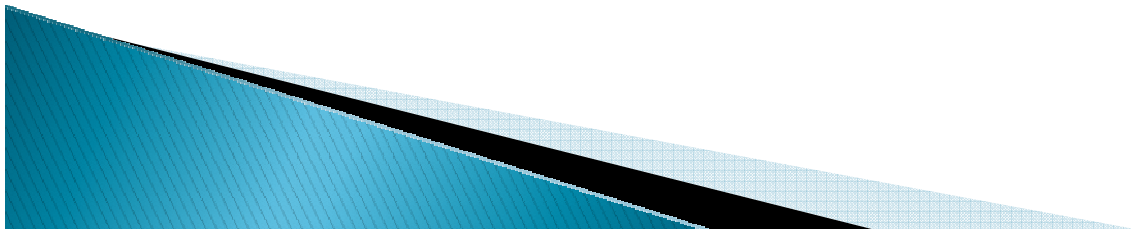
Zimbabwe compulsory licensing

- ▶ In 2002 the Minister of Justice, Legal and Parliamentary Affairs declared a period of emergency due to HIV/AIDS pandemic valid for 6 months. The intention was to utilize this option to improve access to ARVs
- ▶ In 2003 the period of emergency was extended by 5 years (- 31 December 2008) and compulsory license was issued to either import or make ARVs
- ▶ This was further renewed by 10 years through SI 49 of 2009: now expiring in 2019



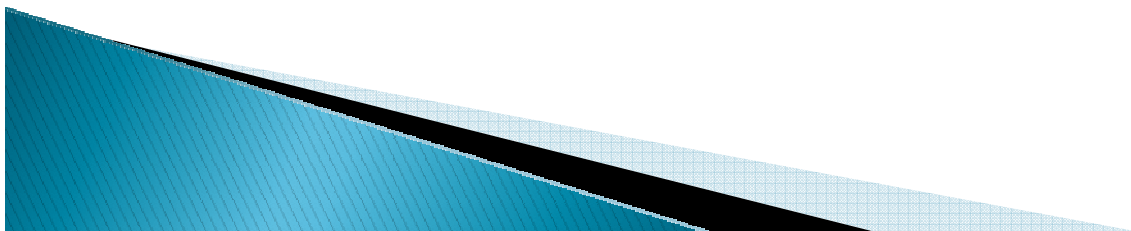
Zimbabwe compulsory licensing

- ▶ In a letter of authorization by the Minister of Justice, Varichem Pharmaceuticals was commissioned to produce ARVs or HIV/AIDS related drugs.
- ▶ They were to supply three quarters of their product to state owned health institutions
- ▶ The ARV roll out program is funded mainly through government budgetary allocations with some assistance from NGOs. In 2003 Varichem's first generic ARV Varivar was launched.
- ▶ Accordingly, the price of AZT/3TC comes down from US\$30 per month to less than US\$15 a month



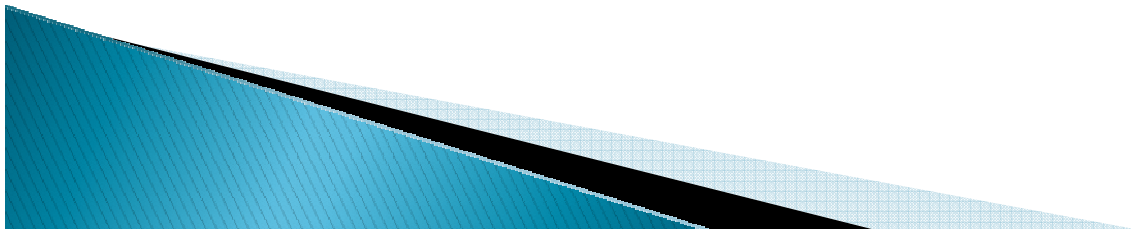
Challenges

- ▶ The blanket approach
 - This discourages patent holders from registering their patents in Zimbabwe
- ▶ High duty and VAT charged on raw materials used to manufacture ARV tend to increase the cost of production and of the end product
- ▶ Lack of market access
 - High cost of drugs
 - Donors prefer to import



Conclusion

- ▶ Compulsory licenses are a powerful tool for reducing prices / increasing access to medicines
- ▶ Compulsory licenses are an effective tool for limiting the impact of certain patents and bringing discipline to the IP industry
- ▶ For compulsory licenses to be really effective, developing countries need develop policies that recognize the importance of innovation and develop capacity for local innovation and production





Willie Mushayi



Deputy Registrar
Zimbabwe Intellectual Property Office
38 Nelson Mandela Avenue
1st Floor Century House East
Harare

Phone: +2634775544-6, 777373

Fax: +2634777 372

Direct: +263775162

Cell: +263773 560 284

E-mail: wmushayi@gmail.com

Innocent Mawire

Principal Law Officer

Ministry of Justice and Legal Affairs

Policy and Legal Research

P. Bag CY 7751

Causeway

Harare

Tel: +263 4 774620-7

Cell: +263 773 712 413

Email: i_mawire@yahoo.com

