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**National legislative changes
and the TRIPs Agreement: A
case study of South Africa**

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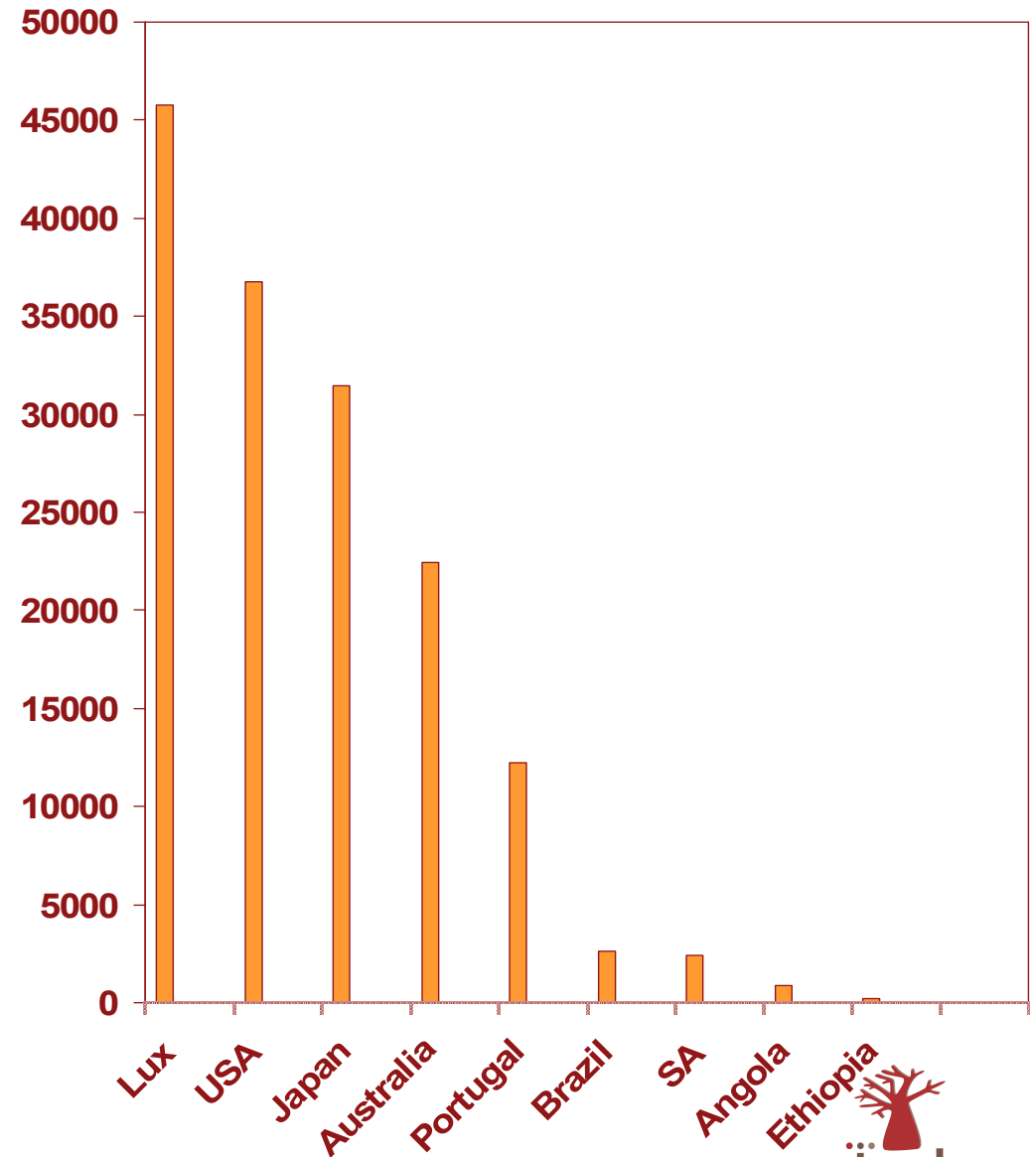
“We are simply asking for fair and equitable rules that would take into account our development needs and allow us to participate fully in the trade system. But instead we risk being pressured once again into accepting rules we don’t need and can’t afford ...”

Ambassador Nathan Irumba, Mission of Uganda and Representative of Least Developed Countries at the WTO

1. Current state of “access to medicines” legislation
2. Existing legislative safeguards in South Africa
3. The need for a comprehensive legal framework
4. Problems for developing countries with making use of TRIPs and other flexibilities
5. Patent Act changes
6. Medicines and drug regulatory legislation
7. Competition Act

Global Ranking of GDP in 2003

- 1 Luxembourg U\$ 45 778
- 4 USA U\$ 36 731
- 7 Japan U\$ 31 433
- 22 Australia U\$ 22 462
- 31 Portugal U\$ 12 200
- 66 Brazil U\$ 2 610
- 68 South Africa U\$ 2 408
- 107 Angola U\$ 892
- 163 Ethiopia U\$ 191



Problems with current patent system

Country	Patents per million of population (1998)
Japan	994
USA	289
Netherlands	196
South Africa	2.5
Brazil	2
Mexico	1

- Graph clearly shows where a strong system of patent protection is most advantageous
- Participation in patent system has had largely negative results for developing countries to date
- Few developing country patent offices conduct patent examinations
- In most instances, development objectives in African countries are constrained by IP protection

- Patents Act
- Section 56 of patents Act contains an ambiguous compulsory licensing provisions (only 4 applications to date)
- Section 4 confers broad discretion to either Minister of Health or Trade to use a patent for public use where necessary
- The Medicines and Related Substances Control Act 101 of 1965 and amendments
- Section 15C allows for both compulsory licensing and parallel importation (not used for CL to date)
- Regulations in terms of S 22(G) make provision for:
 - a) single exit price
 - b) uniform dispensing fees
- Court case has frozen regulations until outcome

- PMA v President of SA
 - Challenge of Section 15C, case abandoned, parallel importation only
- Hazel Tau v GSK and BI
 - Complaint to competition commission, found guilty of excessive pricing, exclusionary act, essential facility
- PSSA v Minister of Health
 - Litigation around medicines Act, single exit price and dispensing fees

- Various pieces of legislation and policies play a role in achieving comprehensive legal framework
- The importance of effective legislation in conducting voluntary negotiations is evident e.g. Brazil for some years
- Use of competition law as a tool in reducing prices
- Drug Regulatory Authority legislation also important given cross cutting nature of access to medicines
- Provisions sensitive to income disparity of people (e.g. royalty provisions)

- Patents Act
- Define health emergency – good opportunity to say who can define emergencies and powers given to government in emergency
- Simplify grounds under which compulsory licensing (S56) can occur
- Express provision on the exportation of generics from South Africa (SA growing manufacturing capacity)
- Favor non-exclusive licenses
- Inclusion of a provision capping royalties to be paid to patent holders (based on UNDP Human Development Index)
- Insertion of a time provision by which negotiations for voluntary license must be concluded

- Limit on dispensing fees
- Limit on single exit prices
 - With purpose of decreasing large mark ups
- Fast-track registration of essential medicines
 - Some cheaper drugs have not been used in government treatment programme because of non-registration
- Enforce “generics first” policy where appropriate
- Transparent procurement policy, mindful of current drug prices and not too long term
- Emphasize the need for harmonisation of DRA rules within SACU to enhance regional co-operation

Competition Act

- Insertion of a provision which allows compulsory licenses on the basis of unfair competition (in line with Art 31(k) of TRIPs and bypassing Art 31(f) and 30 August Decision)
- Insertion of a provision on royalties similar to one in patent Act
- Insert a provision specifically authorizing a competition authority to issue a compulsory license (current Act does not expressly confer this authority)

- Legislation and policies must take into consideration SA's developmental needs
- Holistic legislative and policy response is important
- Increase capacities of drug regulatory authorities
- Legislative reform should ensure that TRIPs flexibilities are maximized
- Avoidance of TRIPs plus legislation
- Technology transfer could be rewarded legislatively (e.g. built into royalty fee structure)
- Any legislative and policy reform should bear in mind international developments (e.g. WIPO development agenda)