

TRIPS

Intellectual Property/Patents Act/

Access to Medicines :

The Case of Zimbabwe

Recent Multilateral and Bilateral Trends in
IP Policy Making; Lessons and Challenges
for Africa:

Tralac Annual Conference

Presented by: Diana Mandaza

6th October 2006

Cape Town, South Africa

Outline of Presentation

- Brief Comments on TRIPS Agreement
- Patent Amendment Bill, 2001
- Patent Amendment Act, 2002
- Declaration of Period of Emergency on HIV/ AIDS Notice, 2003
- The Future

TRIPS Agreement

- Signed on 15 April 1995
- Into force on 1 January 1995
- Countries to be compliant by
 - 1996 Developed Countries
 - 2000 Developing Countries
 - 2006 Least Developing Countries
 - 2016 Extension for Least Developing Countries

Patents Act

New Section Inserted

- New Section 2A
- Inventions for which patent may not be granted
- Diagnostic, therapeutic or surgical methods for the treatment of human beings or animals

Early Working of Patent Provisions

- Section 24 – Extent, effect and form of patent
- Effect of patent – to grant the patentee full power, sole privilege and authority ... so that he enjoys the whole profit and advantage

Section 24(5)

- The rights granted in subsection (4) shall not be construed as prohibiting any person from making, constructing, using or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law that regulates the manufacturing, construction, use or sale of any product.

Section 24(6)

- The rights granted in subsection (4) shall not have effect in relation to a product which has been put on the market in any country by the patent holder or by an authorised person.

Early Working of Patented Products

- Section 24B
- Test Batches of Patented Products
- ... without the consent of the patentee six months before the expiry of the patent
- Production and stockpiling before expiration of patent not consistent with TRIPS
- Working of patent consistent with TRIPS

Parallel Importation of Patented Products

- Section 24A
- A patented product which has been put on the market in another country by a patentee may be imported ... without the consent of the patentee ...

Compulsory Licences in Respect of Dependant Patents

- Section 30A
- Application to be made to Registrar of Patents
- Licence issued by Registrar of Patents

Compulsory Licences

- New provision authorises licences to be issued by Registrar
- Article 31 of TRIPS
- Permits States to grant compulsory licences on grounds determined by a member country
- Right to use patent without the consent of the patent holder
- Compensation to proprietor of patent

Section 31

- Compulsory licence in case of abuse or insufficient use of patent rights
- Proposed new paragraphs (g), (h), (i) and (j)
- Licence now granted by Registrar of Patents

Compensation & Compulsory Licences

- Proposed new Section 31(8)(b)
- Maximum royalty
- Reasonable royalty
- Article 31(h) of TRIPS

Anti-Competitive Practices

- The need to correct anti-competitive practices
- Remuneration may be reduced or excluded where the licence is granted to remedy anti-competitive practices

Use of Patented Inventions for Service of the State

- Section 34
- Agreement of patent holder
- Agreement of Intellectual Property Tribunal
- Article 31 of TRIPS
- Promptly inform patent owner of use

Special Provisions as to State During Emergency

- Section 35
- “(b) for the maintenance of supplies and services essential to the well-being of the community; ”
- Proposed clauses
- For promoting public health and nutrition
- For public non-commercial use

Intellectual Property Tribunal

- Court of record
- President equivalent to High Court Judge
- Powers similar to High Court
- Costs similar to High Court

Declaration of Period of Emergency of HIV/ AIDS Notice, 2003

- Period of emergency 1st January 2003 to 31 December 2008
- Minister empowered to issue authorizations to persons -
 - to make or use a patented drug
 - to import generic drugsfor treatment of persons suffering from HIV/ AIDS-related conditions.

Compensation

- Regulations
- Guidelines from Ministry
- Be guided by experience of other countries

The Future

- Pursue Flexibilities in TRIPS
- DOHA Declaration
- Decision of 30th August 2003
- Supply to the Region
- Regional cooperation

THANK YOU