



REPUBLIC OF SOUTH AFRICA



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

***Topic 7: Flexibilities Related to the Definition of Patentable
Subject Matter***

**Durban, South Africa
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Flexibilities Related to the Definition of Patentable Subject Matter

**Presented at Regional Seminar for Certain
African Countries on the Implementation
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Outline Of Presentation

- Introduction
- The Patent Act Cap. 401
- Patentable Subject Matter
- Exclusions (from Patentability)
- The Proposed Patent Bill
- conclusion

: The Patent Act

- Patent protection in Zambia is governed by the Patents Act Cap. 401 of the laws.
 - The Period of protection is 16 years
 - Patentability in Zambia is based on:
 - **Novelty**
 - **Inventive Step**
 - **Industrial Applicability**
 - **Modification or improvement on an existing Patent**
Section 31

Patentability Criteria

- TRIPS: Art 27.1:
 - Invention has to be new, involve inventive step and be capable of industrial applicability
 - **Broad definition for novelty** – leaving room for members states to define novelty in their laws
 - **High standards on inventive step** – encourages member states to grant strong patent
 - **Strict concept of industrial applicability** – prevent monopolies on research tools and basic research

Patentability Criteria – cont'd

- Patent Act Cap 401 of the laws of Zambia
 - Novelty / prior art:
 - **Known, worked or used** in the territory
 - Including in non-public patent files
 - **Any publication** of which a **copy exist in territories**
 - With respect to 'New Use Patents': Section. 18 (c) : Excluded from patentability: If the invention is a **food or medicine** and only a **mixture of known ingredients**

Patentability Criteria – cont'd

- Proposed Patent Bill in Zambia
- Is clear and specific:
 - Prior art:
 - everything disclosed to the public
 - anywhere in the world
 - by publication in tangible form or by oral disclosure
- Make specific reference to:
 - Inventive Step and industrial applicability are basic requirement for new use patents
 - Traditional knowledge and Genetic Resources used to derive patents

Patentability Criteria – cont'd

Inventive Step

- Patent Act Cap 401
 - Invention has to be non-obvious
- Proposed Bill:
 - Has specific criteria for inventive step – or non-obviousness:
 - any invention that any person who is skilled in the art could derive from prior art (one piece of prior art or a combination of different pieces thereof) is obvious
 - with respect to pharmaceutical field: new dosage, combinations, compositions, etc. that have close chemical compositions to prior art cannot be considered as non-obvious

Exclusion from Patent Protection

- TRIPS provides flexibilities through:
 - Patentability criteria
 - Art. 27.3:
 - a) diagnostic, therapeutic and surgical methods
 - b) plants and animals other than micro-organisms
- Patent Act Cap 401:
 - Section 18: excludes based on:
 - a) Frivolous grounds
 - b) Against morality
 - c) If the invention is a food or medicine and only a mixture of known ingredients
 - + (discoveries / theories / animals and plant varieties / diagnostic, therapeutic methods for treatment of humans & animals)

Exclusion from Patent Protection – cont'd

- Proposed Patent Bill:
 - The Proposed Patent Bill is very precise on this matter:
 - The following are excluded
 - therapeutic and surgical methods
 - biologically occurring plants and animals,
 - Basic research etc.
 - Has transitional period on pharmaceuticals Patent until 2016.

General Exceptions

- TRIPS

- Art. 30 allows for limited exceptions
- Three exceptions with regard to public health:
 - Prior use: prior (secret) users can continue
 - Experimental use: allows for research to be carried out with respect to invention under patent – allows for timely launch of specialized drugs
 - Bolar exemption: to seek marketing approval before patent expired – allows for timely entry of generic into market

General Exceptions

- The Patent Act Cap 401:
 - None of the three exceptions exist in Zambian Patent Act
- Proposed Patent Bill:
 - Prior use: prior (secret) users can continue to do so
 - Experimental use: allows for research to be carried out with respect to invention under patent – allows for timely launch of specialized drugs
 - Six months exhibition clause (if exhibition was not for commercial purposes)

Non-voluntary licenses

- TRIPS

- Art 31: allows government to issue license without patent holder consent.
- Does not define the grounds for issuance of license
- WHO study lists seven state practices:
 - refusal to license
 - public interest
 - public health and nutrition
 - national emergency or situations of extreme urgency;
 - anti competitive practices;
 - dependent patents;
 - failure to exploit or insufficient working.

Non-voluntary licenses

- Patent Act Cap. 401
 - 6 of 7 state practices exist in the Zambian Patent Act
 - Section 37 allows third parties to apply for CL, if:
 - Unable to obtain a license under reasonable terms
 - After 3 years of filing (four years application)
 - Applicant has to inform patent holder
 - Has to provide appropriate compensation (defined by High Court)
 - Patent holder has right to appeal

Non-voluntary Licenses

- Grounds for use of Section 37:
 - lack of local working,
 - lack of sufficient domestic supply (through import or local working),
 - if a patent prejudices trade and industry in Zambia
 - unfair conditions attached by the patentee and the abuse of monopoly rights

Non-voluntary licenses

- Section. 38: Food and medicine products
 - High Court should order license if application by any person interested is made (unless believes there are good reasons for refusing application):
 - For inventions that can be used in food or medicine or production thereof
 - a process for producing such a substance as aforesaid;
 - Any invention that can be used as surgical / curative advice
 - No three (four) year grace period

Non-voluntary licenses

- Section. 40 Government Use:
 - Very wide spectrum
 - Minister may allow any government department to make use of patented invention
 - Government Use includes supply to other countries for defence purposes
 - Government has to inform patent holder *as soon as practicable*
 - Can agree on terms after license issued
 - No three (four) year period

Non-voluntary licenses

- **Section. 41 Government Use in Emergency**
 - Minister has to declare period of emergency by statutory notice among other for:
 -
 - **maintenance of supplies** and services essential to community
 - for **promoting the productivity** of industry, commerce and agriculture;
 - for redressing the **balance of trade**;
 - for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Her Britannic Majesty's dominions or any foreign countries that are in grave distress as the result of war
 - Three (four) year grace period does not apply
 - Patent holder has right to appeal (Art. 42)

Parallel Import

- TRIPS:
 - Art 6: Members are allowed to define own exhaustion regime
 - Three exhaustion regimes are possible:
 - International
 - Regional
 - National

Parallel Import

- Patent Act Cap. 401
 - No provisions included in the statute
- Proposed Patent Bill:
 - International
 - Regional
 - National

Patent Term and Patent Term Extension

- TRIPS
 - 20 years
- ARIPO
 - 20 years (Section 3.10)

: Patent Term and Patent Term Extension

- Patent Act Cap 401:
 - 16 years (Section. 29)
 - Allows for patent term extensions (Section. 30) of five years (ten in exceptional circumstances), if:
 - Patent holder has not received adequate remuneration
 - Due to 'hostilities or other special circumstances' he suffered loss or damages
- Proposed Patent Bill
 - patent term to 20 years
 - No patent term extension

Conclusion

- Zambia realized that most the provisions in the Patent Act Cap. 401 fall short of the requirements of the TRIPS Agreement.
- In the proposed Patent Amendment Bill Zambia has taken on board the minimum requirements on Patentability in accordance with Article 27 of the TRIPS Agreement.
- The Proposed Patent Bill is before Parliament and will be passed for enactment soon.
- Zambia has also taken on board the exclusions as provided by Article 27(3)(a) of TRIPS

The End

- Thank you!!!!

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