



## **WIPO Sub-Regional Workshop on Patent Policy and its Legislative Implementation**

***Topic 4: The patent system and its relationship with other public policies. Policies on the agricultural sector***

**Basseterre, Saint Kitts and Nevis  
April 10 and 11, 2013**

# WIPO Sub-Regional Workshop on Patent Policy and its Legislative Implementation

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Topic 4:  
The Patent System and its  
relationship to the Agricultural Sector

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# Objectives of Session

- To engender an understanding among participants of –
  - the ways in which the patent system – in particular, the patent provisions of the TRIPS Agreement, are relevant to the agricultural sector
  - The issues to be addressed by CARICOM states in formulating patent policy and implementing patent law in order to support and safeguard the agricultural sector

# Approach

- Patent system:
  - Essential elements; Rationale
- Provisions of TRIPS Agreement that affect Agricultural Sector
- Major Concerns
- Implementing TRIPS Flexibilities to address concerns
- Suggestions for IP Policy in relation to Agriculture

# Essential elements of patent system

- A **patent** confers exclusive rights on an inventor or assignee for a limited period in exchange for the public disclosure of the invention
- A patent is granted by the state
- The invention is a solution to a specific technological problem and may be a product or a process.

# Essential Elements of the Patent System

## Rationale for granting patents

- Reward/ Incentive for innovation for the greater public good
- By conferring temporary market exclusivities, patents allow patentees to recoup the costs of investment in R&D and reap a profit, in return for making publicly available the knowledge on which the invention is based

“Bargain struck by society”

# Essential Elements of the Patent System

To qualify for patent protection an invention must be:

- new,
- have an inventive step and
- be capable of industrial application



# Essential Elements of the Patent System

- Rights of patentee : exclusive rights to prevent others from exploiting the patent without authorization- make, sell, use, import etc.
- Rights under a patent may licensed, sold, assigned, willed (property right)

- Exceptions to Infringement - Balance of private and public interests
- Infringement – where a person does any unauthorized act with respect to the rights covered by the patent
- Infringement actionable by civil suit

# Essential Elements of the Patent System

- Patents like all IPRS are territorial
- International dimension: multinational, regional and bilateral treaties

# Essential Elements of the Patent System

The patent system is the framework for the growth of the biotechnology, computer technology, pharmaceutical and seed industries

All of these industries are relevant to the Agricultural sector

# RELEVANT PROVISIONS OF TRIPS AGREEMENT

- Preliminary Points:

IPRs were originally conceived for innovations in manufacturing (such as new machinery, industrial products and processes)

In pre-TRIPS era, countries had greater scope to fashion their IP laws as appropriate to their level of development

# RELEVANT PROVISIONS OF TRIPS AGREEMENT

The Agreement for the Trade –Related aspects of Intellectual Property Rights- TRIPS- was concluded in 1994 and is an Annex to the WTO Agreement arising out of the Uruguay Round of Negotiations

## Deadline for Implementation

- Developed countries: up to January 1, 1996
- Developing countries and countries in transition to market economy to a market economy – up to January 1, 2000
- LDC – 2006 extended to July 1 2013 & until January 1, 2016
- for protection and enforcement of patents and test data in the pharmaceutical sector

# RELEVANT PROVISIONS OF TRIPS AGREEMENT

- TRIPs – minimum standards of IP protection which all WTO members must accord to each other based on principle of national treatment
- Most-favoured nation (MFN) principle also embedded in Agreement
- Generally accepted that standards established by TRIPS more closely related to those that obtained in developed countries

# RELEVANT PROVISIONS OF TRIPS AGREEMENT

## Art. 27.1

“... patents shall be available for:

- any inventions,
- whether products or processes
- in all fields of technology,

provided that they are new, involve an inventive step and are capable of industrial application.

“... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.



# RELEVANT PROVISIONS OF TRIPS AGREEMENT

- Members must require applicant for patent to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art
- Members may require applicant to disclose best mode of carrying out invention & to disclose information on foreign applications and grants

Art 29

## TRIPS: Art 27.2 Key provision

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* (i.e. *general security, matters threatening the social structure*) or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, ...

# TRIPS AGREEMENT: Key provision: Art. 27.3

- 3. Members may also exclude from patentability:
  - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
  - (b) plants and animals (other than micro-organisms) and essentially biological processes for the production of plants or animals (other than non-biological and microbiological processes)
- However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. ...

# Art 27

Summary:

1) Member states need not provide patent protection for plants, animals or essentially biological processes for producing plants and animals

# Art 27

But Member states:

**2) Must accord patent protection to: Microorganisms**

- non-biological processes for producing plants and animals
- microbiological processes for producing plants and animals

**3) Must accord some form of IP protection to plants-  
i.e. by patents, a *sui generis* system or by both the  
patent system and a *sui generis* system**

# Art 27

- Implications

product patents for proteins, vectors ,  
microorganisms, parts thereof, including  
genes (unless the latter are contained in a  
plant),

process patents for processes for the  
production of plants by non-conventional  
breeding techniques including genetic  
engineering.

# Concerns Relating to the Agricultural Sector

## 1. Food security

- access to and affordability of protected products (higher prices for seeds and other agricultural input)
- concentration of agricultural production
- Reduction on flow of germplasm
- threat to crop diversity

# Concerns

2. Effect on research on plant genomics: patents are widely used to protect the technologies that are employed in this research

3. Inappropriate use of plant and animal genetic resources (biopiracy)



# Concerns

- 4. Farmers' Rights

Arises in context of sui generis system one of the questions that arises – farmers' rights

- -i e. how the contribution of farmers to the conservation and development of plant genetic resources should be recognised and preserved.
- traditionally – it was the process of selection and experimentation by farmers that led to varietal and cultural improvements in plants.

# Concerns

- Pharmaceutical – herbicides, fungicide etc. needed in agriculture: patent protection -- increased costs
- Livelihood of small farmers/rural poor – destruction of the independence and sustainability of rural farmers mainly in developing countries

# Patent policy & Legislative Implementation

Ques: Whether patent aspects of the TRIPS agreement can be implemented in a manner that reduces possible detrimental effects of the levels of protection required by the TRIPS Agreement, in particular, those aspects that affect agriculture?

``Flexibilities`` in the Agreement have been identified by various scholars and experts.

# Patent policy & Legislative Implementation

The term “flexibilities” means that “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

# Patent policy & Legislative Implementation

Flexibilities in the Agreement could exist because,  
*inter alia*

- Subject - Matter not addressed
- Influence of Objectives and Principles on interpretation of Agreement
- Subject-matter specifically excluded
- Scope of obligations limited
- Provisions are optional
- Exceptions to Obligations
- Terms /concepts not defined
- Transitional Provisions

# Flexibilities

- A CDIP has grouped the aspects of the TRIPS Agreement that offer opportunities for laws to be drafted to take advantage of flexibilities:
  - (i) in the process of the acquisition of the right;
  - (ii) defining the scope of the right; and
  - (iii) when enforcing the rights

**(CDIP/5/4)**

# Flexibilities

## (i) Acquisition of rights- Patent law

A. Could provide for more fulsome disclosure of the patent than the minimum level required under Art. 29 TRIPS: E.g.

- require the description of the process of making the claimed product or parts of the product;
- demand that the disclosure be adapted to the technological level of the country
- restrictively define novelty, microorganism, inventive step

B. Invention could be defined to make it clear that it does not include things found in nature such as genes or genes sequence

# Flexibilities

- (ii) Flexibilities related the scope of the patent right  
Patents laws may provide for –
  - use of patented invention for experimental purposes and for obtaining data necessary for anticipating market approval
  - use of compulsory licences (confirmed by the Doha Declaration on the TRIPS Agreement and Public Health -that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.)
  - Most advantageous type of exhaustion of patent rights (Art. 6)



# Flexibilities

- (iii) Enforcing Rights
- Where damages are provided for infringement of patents law could limit the award of damages to those cases in which the infringer “knowingly, or with reasonable grounds to know, engaged in infringing activity”.

# Flexibilities

Other possibilities:

- Restrictive definition of microorganisms;
- Strict standards of novelty, inventive step and industrial application
- Excluding from patentability new uses of known products; plant varieties

# Flexibilities

- Requirement of disclosure of access to genetic resources, in order to ensure compliance with access and benefit sharing requirements

# Flexibilities

Plant protection: 3 options

- 1) Patents; 2) *sui generis* system based on UPOV system; 3) another *sui generis system*

## **Recommendation:**

Developing countries should generally not provide patent protection for plants and animals, as is allowed under Article 27.3(b) of TRIPS, but a non-UPOV system tailored to their specific needs

# Flexibilities

- Such a *sui generis* regime should permit access to the protected varieties for further research and breeding, and provide at least for the right of farmers to save and plant-back seeds, including the possibility of informal sale and exchange.

# Flexibilities

- Research exception: non-infringing use of the patented product for scientific experimentation during the term of the patent and without consent

(See e.g. laws of Barbados, Belize, Dominica, Grenada, St. Lucia, Trinidad and Tobago)

# Flexibilities

Patent laws may include matters not covered and not precluded by the TRIPS agreement: scholars have identified e.g.

- utility models;

- disclosure of origin of genetic material and prior informed consent, and traditional knowledge & folklore

# Flexibilities

The following “general” flexibilities if reflected in law could also be beneficial to agri. Sector-

**Objectives: Art 7** (promotion of technological innovation/ the transfer and dissemination of technology)

**Principles Art 8:** (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,)



- Exceptions (Art. 30)
- Compulsory Licences (Art 31)

# Agricultural policies and IPRS

- As far as I am aware no CARICOM state has integrated IPRS in their policies on agricultural
- In official systems disconnect between the two systems
- Call for inter-sectoral, inter- Ministerial approach as IPRS cross-cutting issue.

# POLICY ACTION REQUIRED

- Need for each CARICOM state to consider policy options and to take the necessary steps at national level to avail itself of flexibilities
- Difficulty - in developing countries, including CARICOM states national interest as it relates to IPRS is not usually articulated.

# POLICY ACTION REQUIRED

Policy- making gap in CARICOM states

- In general, no clear policy or strategy regarding the use of IPRs generally or patents specifically in development (But note Vision 2020 (Trinidad); & Vision 2030 (Jamaica))
- Little or no interface between IPRs /patent policy and agricultural policy- disconnection

# POLICY ACTION REQUIRED

- What is required: coherent and comprehensive policy on role of IPRs in agriculture and IP strategy
- Integrated approach which establishes linkages between policies and laws relating to:
- Patents, plant varieties (*sui generis*), geographical indications and the protection of biodiversity

# POLICY ACTION REQUIRED

- Thoughtful and deliberate legislative agenda which sees the implementation of patents and other IP laws enacted not only to satisfy international obligations but tailored to suit the specific needs of each country and, where applicable, the Region

*End*