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Intellectual Property Protection of Traditional Knowledge: The Malaysian Experience

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Genetic Resources as a Source of Wealth

- Biotechnology – the New Wealth Creator
- “An ethical battle rages as prospectors scour the globe to find - and profit from - organisms that could cure some of the world’s worst diseases”. (Dealing in DNA , Tim McGirk, TIME, November 30, 1998, p 58)
- “... Organisms that are of no apparent use may be tomorrow’s saviours.” (The Value of Biodiversity, Rick Cannell, Financial Times, July 21, 1998)
- “Scientists ... realise that forests and oceans hold a bounty of useful chemicals - " (Nature's Drug, William Underhill, Newsweek, November 7, 2005, p 50)

The Relevance and Value of Traditional Knowledge

- The three strategies for collecting plants for screening programs:
 - random,
 - taxonomic and
 - ethnobotanical.
- In relation to the ethnobotanical strategy, TK associated to biological or genetic resources, or traditional medicines are relied upon by bioprospectors as valuable leads to identify plants or animals that can be used as raw materials to obtain beneficial effects

The Relevance and Value of Traditional Knowledge

- Therefore, TK has economic value.
- But TK is easily copied – eg, a member of an indigenous tribe shows a bioprospector a plant that he uses on patients who complain of headache.
- The bioprospector does not need further instruction to understand that plant contains a potentially useful active ingredient.

FAO International Undertaking 1983

- Article 1 of the FAO International Undertaking on Plant Genetic Resources declares:
- The objective of this Undertaking is to ensure that plant genetic resources of economic and/or social interests, particularly for agriculture will be explored, preserved, evaluated and made available for plant breeding and scientific purposes. This Undertaking is based on the universally accepted principle *that plant genetic resources are the heritage of mankind and consequentially should be available without restriction.* (emphasis mine)

Convention on Biological Diversity 1992

- Article 3 of the United Nations Convention on Biological Diversity (CBD) states :
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- "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction."

Paradigm Shift

- From Common Heritage
 - unrestricted access
- To National Sovereignty
 - controlled access (CBD 1993)
 - Prior informed consent
 - Benefit sharing
- In relation to traditional knowledge:
 - “equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”

Mandatory Obligations under TRIPS - 1

- Art 27(1) - ... patents shall be available for any inventions, whether products or process, in all field of technology, provided that they are new, involves an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology ...

Mandatory Obligations under TRIPS - 2

- Art 29 – Conditions on Patent Applicants
- (1) Member shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art
- Question: Should the patent application be required to contain disclosure of information relating to source of genetic resources, evidence of prior informed consent and benefit sharing?

Conflict in the International Arena?

- The World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994
 - Obligates
 - Private rights
- Convention on Biodiversity (CBD) 1992
 - Empowers
 - Public rights

Protection of TK and GR - Work in Different Fora

- Convention on Biological Diversity 1992
- Nagoya Protocol on Access and Benefit Sharing 2010 [Note: As of June 2011, the Protocol has 24 signatures and no ratifications to date. The Protocol will enter into force on the 90th day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession by states or regional economic integration organizations that are parties to the Convention]
- World Trade Organisation – TRIPS:
 - Efforts to add a new Article 29bis to the TRIPS Agreement
- World Intellectual Property Organisation
 - Negotiation for an International Agreement for the protection of genetic resources, traditional knowledge and folklore

Are TK and GR protected under our Intellectual Property Laws?

- Are Traditional Knowledge and Genetic Resources protected under our Intellectual Property Law?
- Note:
- Genetic resources per se, as encountered in nature, are not IP.
 - Since they are not creations of the human mind they cannot be directly protected as IP.
- In Malaysia, as yet, there is no specially enacted legislation to protect traditional knowledge.
- Also, generally there is no incorporation of TK related provisions into the current IPR legislative framework except in relation to the Plant Variety Protection legislation.

Malaysia's Response to the CBD - Policies

- Policies:
- Malaysia has already in place several policies related to biodiversity conservation and sustainable use:
 - National Policy on Biological Diversity,
 - National Forestry Policy,
 - National Policy on Environment and
 - National Policy on Wetlands,
 - National Biotechnology Policy, 2005
 - etc

Malaysia's Response to the CBD - Policies

- National Policy on Biological Diversity 1998
- Strategy VIII: Review legislation to reflect biological diversity needs legislative framework
- Among Programmes and Activities:
 - Reviewed legislations – eg Wildlife Protection Act 1972 is under review to include more holistic biodiversity management
 - Proposed Biosafety Bill by Ministry of Natural Resources and Environment [Enacted Biosafety Act 2007, wef from 1 December 2009]
 - Proposed ABS Bill [Access to Genetic Material Bill] by Ministry of Natural Resources and Environment
 - Proposed Plant Variety Protection Bill [Enacted Protection of New Plant Varieties Act 2004,wef from 20 Oct 2008]

Legislative Response to the CBD – Federal Level

- Legislative Framework:
- In Peninsular Malaysia, currently there is no dedicated law on the protection of genetic resources and traditional knowledge and access and benefit sharing (ABS).
- All the biodiversity related law were legislated prior to the CBD and their main objectives are in relation to the preservation, protection, utilisation and management of the flora and fauna of the country. For example:
 - National Forestry Act 1984, Act 313
 - National Parks Act 1980, Act 226
 - Protection of Wild Life Act 1972, Act 76
 - Fisheries Act 1985 - Act 317 etc

Patents Act 1983

- Patent

- Universal novelty system – prior art consist of everything disclosed to the public however disclosed
- So no possibility of oral or “unfixed” traditional knowledge been patented - orally disclosed TK is recognized as prior art in the patent law system
- However, absence of provisions requiring prior informed consent and evidence of benefit sharing, procedure for examining TK related patent application
 - so inventions that were derived from TK may be patented if it satisfies the novelty and inventive sep requirements.

Protection of New Plant Varieties Act 2004

- Preamble to the Act states, inter alia, that the objectives of the Act is, inter alia, to provide for the recognition and protection of contributions made by farmers, local communities and indigenous people towards the creation of new plant varieties.
- Section 12 of the Act specifies the information and supporting documents that need to be disclosed by the applicant for purposes of application.
 - PIC - In relation to cases where the plant variety is developed from traditional varieties, the prior written consent of the authority representing the local community or the indigenous people is required.

Protection of New Plant Varieties Act 2004

- There is also a need to furnish information:
 - Relating to the source of the genetic material or the immediate parental line of the plant variety.
 - Documents relating to the compliance with any law regulating access to genetic or biological resources
 - Also documents relating to the compliance of any law regulating activities involving genetically modified organism in cases where the development of the plant varieties involves genetic modification.

Protection of New Plant Varieties Act 2004

- Effect of non compliance?
- Section 23 - one of the grounds of opposition - that the application for registration of the new plant variety and grant of a breeder's right does not comply with the requirement of the Act.
- Also under section 39(2) of the Act in relation to invalidation, the grounds included:
 - a. that the holder has furnished to the Board false or misleading information or statement in respect of the application for registration of the new plant variety and grant of a breeder's right.
 - b. that the holder has not complied with the requirement of the Act.

Economic Planning Unit Guideline

- Circular No. 3/1999 - Regulations for the Conduct of Research in Malaysia
- This is a general circular regulating certain researches in Malaysia, and is not specific to researches relating to the natural sciences.

Legislative Response to the CBD – State Level

- Unlike West Malaysia, the states of Sabah and Sarawak have already enacted their own legislation to protect biodiversity which incorporate the ABS elements of the CBD.
- Note: Although not enacted to protect traditional knowledge as such but to incorporate the ABS elements of the CBD, the above two states have enacted laws which impact on the protection of traditional knowledge.
 - 1. Sarawak Biodiversity Centre Ordinance 1997
 - 2. Sarawak Biodiversity Centre (Amendment) Ordinance 2003
 - 3. Sarawak Biodiversity Regulations 2004
 - 4. Biodiversity Ordinance Sabah 2000

State Level - Sarawak

- Sarawak Biodiversity Centre Ordinance 1997
- Section 35, among others, provides for regulations to be made in respect of the terms and conditions for access to and use of the biological resources of the State or such resources, data, exhibit, information or material kept, stored or maintained in the Biodiversity Centre, and permits to be issued under the Ordinance.
- Pursuant to section 35 of the Ordinance, the Sarawak Biodiversity Regulations, 2004 were made.

State Level - Sarawak

- Sarawak Biodiversity Centre Ordinance 1997
- Under the Regulations no permit for access to, collection of and research on protected biological resources shall be issued until the applicant signs a research agreement with the Government as provided in regulations 6 and 21
- One important term to be included in the agreement is in relation to the rights of the Government to patent and intellectual property to or over any discovery resulting from the research undertaken, and where appropriate, the sharing of such rights with other parties to the research agreement.

State Level - Sarawak

- Sarawak Biodiversity Centre Ordinance 1997
- Ethnobiological research is regulated under Part VI of the Regulations.
- Besides the requirement for a research agreement, the permit holder may be required to make payment to the natives as reward for the knowledge or information provided by them in connection with the research. Such payment may be made regardless of whether such research results in the commercial development of any medicinal or other products.
- In addition to the above payment, where the research leads to the development of any pharmaceutical or medicinal compounds etc, the patent or intellectual property right to such products shall be shared with the natives involved in the research.
- **PROBLEM:** No nexus to the Patents Act

Regional Initiatives – ASEAN Framework Agreement

- In September 1997, at the eighth meeting of the ASEAN Senior Officials on Environment, “the Philippine delegation proposed the formulation of a common protocol among ASEAN member countries on access to genetic resources and IPRs.”
- Two Technical Expert’s Meetings were held resulting in the draft ASEAN Framework Agreement on Access to Biological and Genetic Resources in February 2000. The draft Framework Agreement was to have been adopted in 2004.

Regional Initiatives – ASEAN Framework Agreement

- *The Key Principles of the Framework Agreement*
- Objectives:
 - Set minimum standards among the parties for regulating ABS arising from the utilisation of, biological and genetic resources, and to strengthen national initiatives towards this objectives
 - Accord recognition and protection to traditional knowledge of indigenous and local communities, and to facilitate the fair and equitable sharing of benefits with the said communities where traditional knowledge is utilised.

Regional Initiatives – ASEAN Framework Agreement

- *The Key Principles of the Framework Agreement*
- Scope and Coverage:
- Covers all biological and genetic resources of the parties, including the traditional knowledge associated therein, with the exclusion of genetic resources of human origin.”
- Not applicable to the traditional uses of biological and genetic resources by indigenous and local communities in accordance with their customary practices and traditions.
- Access to biological and genetic resources shall not automatically mean access to the traditional knowledge associated with the resources. Access to such traditional knowledge shall be explicitly indicated in the application for access.

Regional Initiatives – ASEAN Framework Agreement

- *The Key Principles of the Framework Agreement*
- Obligations of the Parties:
 - Among other responsibilities, the Parties are obliged to:
 - (a) take legislative, administrative or policy measures to regulate ABS arising from the utilisation of biological and genetic resources in accordance with the Agreement, and
 - (b) establish procedures for the granting of prior informed consent at the national and local level with the direct involvement of resource providers.

Regional Initiatives – ASEAN Framework Agreement

- *The Key Principles of the Framework Agreement*
- Prior Informed Consent:
- Prior informed consent of the party providing the biological and genetic resources is necessary before the access can take place.
- All applications for prior informed consent shall be accompanied by a full disclosure of prescribed minimum information

Regional Initiatives – ASEAN Framework Agreement

- *The Key Principles of the Framework Agreement*
- Fair and Equitable Sharing of Benefits:
- All resource providers shall be actively included in the negotiation of benefits on the basis of a full disclosure of potential benefits and risks arising from the use of the biological and genetic resources.
- Where traditional knowledge and resources are involved, Parties are to establish processes to ensure the fair and equitable sharing of benefit arising from the use of such traditional knowledge and resources.

Regional Initiatives – ASEAN Framework Agreement

- *The Key Principles of the Framework Agreement*
- Cross Borders Endemic Species :
- Whenever biological or genetic resources are indigenous to two or more Parties and such resources are subject to bio prospecting, the Parties where such resources are found may collectively discuss, with the entity initiating the bio prospecting activity, the terms and conditions of access to and benefit sharing arising from the utilisation of such resources.
- This arrangement will be facilitated by the clearing house mechanism.

Regional Initiatives – ASEAN Framework Agreement

- *The Key Principles of the Framework Agreement*
- Regional Clearing House Mechanism :
- Responsibility for, inter alia:
 - a. providing relevant information subject to appropriate confidentiality provisions, and such terms and conditions that may be imposed by a Party which provided such information;
 - b. providing technical and legal support to the competent national authorities;
 - c. establishing a database of biological and genetic resources and their associated traditional knowledge of the Parties, subject to national arrangement;

Regional Initiatives – ASEAN Framework Agreement

- *The State of Play*
- ASEAN Annual Report 2010 – 2011 – no mention

Concluding Remarks

- Protecting TK and GR:
- Three main options possible:
 - i) To maintain the status quo
 - ii) To revise the existing IP laws to make them more amenable to the protection of TK
 - iii) To have a sui generis law recognizing the right of indigenous people to communal property over their TK and GR

Concluding Remarks

- Concluding Remarks
- Need to have a regional mechanism for solving dispute relating to:
 - Cross Borders Endemic Species
 - Shared traditional knowledge
 - Shared cultural expressions
- To minimise instances of these happening between neighbours:
 - 2007 - Rasa Sayang, batik and wayang kulit
 - 2009 - Pendet dispute
 - 2012 – Tor Tor dance

END

- Thank you for your kind attention