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Review of Article 27.3(b), the Relationship between the TRIPS Agreement and Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore

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Health and Environment Policy for Asian and Pacific
Region***

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Outline of Presentation

- Background: Article 27.3(b); Rio Earth Summit, CTE; Seattle Ministerial; Doha mandate.
- Organization of work since Doha
- Substantive issues and positions
 - Review of Article 27.3(b)
 - Relationship between TRIPS and CBD
 - Protection of traditional knowledge and folklore



Background on TRIPS-CBD discussions in the WTO

- Discussion on the TRIPS-CBD began in the WTO in the Committee on Trade and Environment in 1995
- Brought into the TRIPS Council through the built-in review of Article 27.3(b) in 1999
- Picked up momentum in the run up to Seattle with proposals on amending TRIPS to include TK submitted by developing country groups. No result at Seattle but was seen as important by all.
- Discussion continued through 2000-2001. GC Special Session on Implementation directed continued examination of the relationship between TRIPS and CBD
- Doha work programme – birth of triplets

Doha Ministerial Declaration

- Doha Ministerial Declaration (WT/MIN(01)/DEC/1, 14 Nov. 2001)
 - Para. 19: “We instruct the TRIPS Council, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore... ”
 - Para. 12: Outstanding implementation-related issues: we agree that negotiations on outstanding implementation issues shall be an integral part of the Work Programme... and that agreements reached at an early stage in these negotiations shall be treated in accordance with the provisions of paragraph 47 below. In this regard, we shall proceed as follows: (a) where we provide a specific negotiating mandate in this Declaration, the relevant implementation issues shall be addressed under that mandate; (b) the other outstanding implementation issues shall be addressed as a matter of priority by the relevant WTO bodies, which shall report to the TNC, established under paragraph 46 below, by the end of 2002 for appropriate action.”
 - Different views on whether or not part of Doha round of negotiations



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Organization of work since Doha

- Para. 19: regular meetings of the TRIPS Council:
 - three separate agenda items on the agenda of the TRIPS Council since 2002
- Para. 12: also took place in the TRIPS Council and was reported upon to the TNC at the end of 2002
 - Since 2003, part of DG consultative process on outstanding implementation issues chaired by DDG
 - From early 2009- 2011
 - DG re-activated fairly intensive consultations chaired by him.
 - The consultations were on two TRIPS-related implementation issues.
 - in-depth Q&A are basis of discussion, and reports to all Members. Gathering information about selected members' national laws, regulations and practices relevant to the discussion.



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TRIPS and CBD



What is the CBD

- CBD: entered into force on 29 Dec. 1993 and 193 Parties as of March 2010
- Three main objectives:
 - Conservation of biological diversity;
 - sustainable use of the components of biological diversity; and
 - Fair and equitable sharing of the benefits arising out of the utilization of GRs
- Most relevant provisions:
 - Art.8(j): in-situ conservation: each contracting Party shall ... respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities, ... and encourage the equitable sharing of the benefits arising from the utilization.
 - Art. 15: access to genetic resources: PIC and ABS
 - Recognizing the sovereign rights of States over their natural resources
 - Access, where granted, shall be on mutually agreed terms
 - Access to GRs shall be subject to PIC of the Contracting Party providing such resources.

What is Nagoya Protocol?

- **Scope:** Applies to **GRs and associated TK** and to the benefits arising from their utilization
- **Main obligations:**
 - **Benefits shall be shared** in a fair and equitable way upon mutually agreed terms with the provider. Each Party **shall take legislative, administrative or policy measures, as appropriate.**
 - **Access to GR and TK to be subject to prior informed consent.** Each Party **shall take measures, as appropriate,** with the aim of ensuring that the PIC or approval and involvement of indigenous and local communities is obtained for GR and TK.
 - To support compliance, each Party **shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of GR, including the use of check points.**
 - Check points **must be effective and relevant** to the utilization of genetic resources ...[and collect information] **at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.**
 - Such information, including from Internationally Recognized Certificate of Compliance (IRCC) where they are available, will, without prejudice to the protection of confidential information, be **provided to relevant national authorities, to the Party providing PIC and to the ABS Clearing-House, as appropriate;**
 - Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance.



TRIPS/CBD – Main issues under discussion

- Compatibility between TRIPS & the CBD
 - Whether or not there is conflict between TRIPS/CBD
 - Whether or not something needs to be done in the WTO on the TRIPS side to ensure mutual supportiveness.
 - If yes, what?
 - Important common ground on key underlying objectives:
 - Importance of TRIPS/CBD being implemented in a mutually supportive way
 - Avoidance of erroneous patents for inventions that use GRs and associated TK
 - Securing effective compliance with national access and benefit-sharing regimes
 - Widely accepted that patent offices need to have necessary information to make proper decisions and patent system's role should not be undermined.
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TRIPS/CBD – Compatibility

- Inherent conflict
 - Need to reconcile TRIPS and CBD as part of the review process by amendment to TRIPS
 - Patents over genetic resources not compatible with sovereignty and a mandatory prohibition of patents on all life forms.
 - A disclosure requirement in TRIPS
- No conflict
 - The two agreements have different and non-conflicting objectives, and they can be implemented in a mutually supportive way at national level.
 - willing to engage constructively on common ground of key underlying objectives
 - Ensuring authorized access and equitable benefit sharing
 - Avoiding erroneously granted patents
- No inherent conflict, but undecided whether international action is desirable
 - Further study is needed, including sharing of national experiences to examine arguments for or against different approaches
- No inherent conflict, but international action desirable in order to ensure or enhance the mutual supportiveness of TRIPS/CBD: 4 disclosure proposals
 - A disclosure requirement on patent applicant is needed
 - 4 disclosure proposals at earlier stage.
 - Amendment to PCT or TRIPS ?
 - Legal effect of failure of disclosure?
 - Mandatory or voluntary ?



Proposals made by one side of the debate: Comparative Table of the Disclosure Proposals (1)

<i>Proposals</i>	Brazil, India, Peru etc.	Switzerland	EC	Norway
<i>Amendment</i>	TRIPS Article 29bis (?)	PCT Regulations	-----	Article 29bis
<i>Elements of disclosure</i>	<ul style="list-style-type: none"> <input type="checkbox"/> The country providing biological resources (BR) and/or associated traditional knowledge (TK), the provider, the country of origin if known after reasonable inquiry <input type="checkbox"/> Evidence of compliance with national regimes <input type="checkbox"/> prior informed consent; <input type="checkbox"/> fair & equitable benefit sharing from commercial or other use 	<ul style="list-style-type: none"> <input type="checkbox"/> source of genetic resources (GR) and TK <input type="checkbox"/> Patent offices should send information received to the country (list of government agencies) 	<ul style="list-style-type: none"> <input type="checkbox"/> country of origin, if readily known. If not, source of GR and related TK <input type="checkbox"/> Patent offices should send information received to the country/CBD Clearing-House Mechanism 	<ul style="list-style-type: none"> <input type="checkbox"/> Source of GR and TK, even if unrelated to GR. Country of origin, if known <input type="checkbox"/> Evidence of compliance with national reqmts. on prior informed consent <input type="checkbox"/> CBD Clearing-House Mechanism
<i>Mandatory or optional</i>	mandatory	Optional at international level, mandatory at national level	mandatory	mandatory



Comparative Table of the Disclosure Proposals (2)

<i>Proposals</i>	Brazil, India, Peru etc.	Switzerland	EC	Norway
<i>Trigger for disclosure</i>	Where invention concerns , is derived from or developed with BR and TK	Where invention is directly based on or makes immediate use + physical access (GR) or is consciously derived (TK)	GR and TK: direct basis & awareness (i.e. know or have reason to know this)	-----
<i>Legal effects of non-compliance: Pre-grant</i>	- to prevent the further processing of applications or the grant of patent;	- Delay of the processing of patent applications;	- Delay of the processing of applications;	- Delay of the processing of applications;
<i>Legal effects of non-compliance: Post-grant</i>	-to revoke ; -to render unenforceable Including in cases of false or fraudulent info.	- invalidation of granted patents, if due to fraudulent intent ; - Could include criminal sanctions, including fines.	- legal effects should be outside the ambit of patent law (civil and/or administrative sanctions).	- legal effects should be outside the ambit of patent law (civil and/or administrative sanctions).



Text of Draft Modalities for TRIPS related issues: TN/C/W/52+Add1-3, July 2008

- Sponsors: proponents of the TRIPS related issues
 - *Albania, Brazil, China, Colombia, Croatia, Ecuador, the EC, Georgia, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Moldova, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group*
- Draft modality text for TRIPS/CBD
 - Amendment: Yes.
 - Mandatory or Optional: **Mandatory**
 - Elements of disclosure:
 - **Country providing/source** of GRs, and/or associated TK (for which a definition will be agreed) in patent applications.
 - Members **agree to define the nature and extent of a reference to PIC and ABS.**
 - Additional elements in Members' proposals such as **PIC and ABS** as an integral part of the disclosure requirements shall be considered in negotiations and
 - **Legal effect:**
 - **Post-grant sanctions**, may also be raised and shall be considered in negotiations.



Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the CBD (TN/C/W/59)

- Sponsors:
 - *Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group and the African Group*
- Draft Decision
 - Amendment: Yes, Article 29bis
 - Mandatory or Optional: **Mandatory**
 - Elements of disclosure:
 - **The country providing** GRs, and/or associated TK , that is, the country of origin, and
 - the source in the country
 - A copy of an IRCC. If an IRCC is not applicable in the providing country, the applicant should provide relevant information as required by the national legislation of the providing country.
 - Legal effect:
 - Shall impose post-grant sanctions which may include administrative/criminal sanctions, fines, adequate compensation for damages or other measures including **revocation**.



Proposals made by the other side of debate

- National based approach by the US
 - IP/C/W/393
- Databases approach by Japan
 - IP/C/W/472 and 504



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- Four clusters of questions proposed by the WTO Members:
 - Legal character of misappropriation
 - Costs and benefits of measures, other than the disclosure requirement, to address misappropriation and benefit sharing
 - Legal scope of the national-based approach
 - Administrative costs and burdens, and legal certainty, of a mandatory disclosure requirement



- Cluster 1: Legal character of misappropriation
 - The definition of misappropriation
 - Illegal or illegitimate acts with respect to the acquisition and use of GRs
 - The definition should not be a precondition for establishing a disclosure obligation
 - Whether access to GRs through channels that are consistent with national laws be considered misappropriation in particular cases?
 - Whether access to a GR or BR can give rise to a claim of misappropriation based on the laws of the country of origin if the resource was obtained from another country?
 - The disclosure obligation would only cover disclosure of the country providing GRs and source of GRs, and the national law of the country of source would apply.



DG Report in April 2011

- Cluster 2: measures, other than the disclosure requirement, to address misappropriation and benefit sharing
 - What provisions, other than disclosure requirements, could ensure that patents are not issued in cases where inventions are based on GRs or associated TK, which have been obtained without proper and legitimate authorization and without equitable benefit sharing?
 - Whether mechanisms to prevent misappropriation of GRs should differ from commercialized products that are patented as against commercialised products that are not patented.
 - Whether and how databases of TK and GRs would achieve the shared objective of authorised and legitimate access to GRs and associated TK
 - Databases approach, which principally addresses erroneously granted patents
 - None of the proposals was a stand-alone response or solution, and they are complementary to each other in a composite package that would overall guard against misappropriation and ensure prior informed consent and equitable benefit sharing.

- Cluster 3: legal character and enforcement possibilities of national based approach
 - How a contract-based system alone address transboundary aspect of access, benefit sharing, and prior informed consent
 - It was acknowledged that a contract-based system may not be sufficient in itself, but it is the single best way to address the ABS and prior informed consent, along with appropriate domestic legislation.



DG Report in April 2011

- Cluster 4 issues concerning administrative costs and burdens, and the legal certainty and predictability, of a mandatory disclosure requirements within the patent system
 - Additional costs and burden of incorporating the mandatory disclosure requirements as compared to existing obligations under Article 29.1 of TRIPS
 - Since there was no details on the design of the disclosure system, there was legal uncertainty and difficulty in weighing costs or burdens, and it would not necessarily bring the intended benefit. One outcome may be litigation between commercial competitors. If the disclosure requirement resulted in a cancellation of patents, it may actually lead to wider commercial exploitation of GRs and TK, still without any benefit sharing.
 - How these costs would be offset against benefits of improving patent examination, facilitating prior art search, promoting transparency, contributing to preventing misappropriation of GRs and TK, and ensuring equitable benefit sharing and prior informed consent
 - Whether a disclosure requirement could be implemented in a consistent manner which would provide legal certainty
 - There would be no difficulty in maintaining coherence between the different forums dealing with this issue, as each was working within its own mandate.



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Review of Article 27.3(b)

Explanation of Art. 27.1, 27.2, & 27.3(a)

- Patentable subject matter (Art.27.1)
 - Any inventions, whether products or processes, in all fields of technology
 - Discovery vs. invention
 - No definition of “invention”
 - Three criteria for patentability: novelty, inventive step (non-obviousness), industrial application (usefulness)
 - Non-discrimination: the place of invention, the field of technology, products imported or locally produced
- Exclusion from patentability (Art.27.2)
 - The commercial exploitation of an invention is contrary to *ordre public* or morality.
 - To protect human, animal or plant life or health
 - To avoid serious prejudice to the environment
- Exclusion from patentability (Art.27.3(a))
 - Diagnostic, therapeutic and surgical methods for the treatment of humans or animals

Explanation of Art. 27.3(b)

- Members may exclude from patentability
 - Plants and animals
 - Essentially biological processes for their production
- Members shall not exclude from patentability
 - Micro-organisms
 - Non-biological and microbiological processes
- Members shall protect plant varieties
 - By patents or
 - By an effective *sui generis* system or
 - By any combination thereof
- Article 27.3.(b) shall be reviewed in 1999: different interpretations of "review"
 - Review of implementation
 - Review with a view to revision



TRIPS Council's Information-gathering Exercise under Art. 27.3(b) (1)

- Illustrative list of questions: IP/C/W/122 and IP/C/W/126
 - Patent protection of plant and animal inventions
 - Protection of plant varieties
- Information from 25 Members: IP/C/W/125 and Add1-24
 - *Australia; Bulgaria; Canada; the Czech Republic; Estonia; the European Communities and their member States; Hong Kong, China; Hungary; Iceland; Japan; Korea; Lithuania; Moldova; Morocco; New Zealand; Norway; Poland; Romania; Slovak Republic; Slovenia; South Africa; Switzerland; Thailand; the United States and Zambia*
- The Secretariat's synoptic tables: IP/C/W/273/Rev.1



TRIPS Council's Information-gathering Exercise under Art. 27.3(b) (2)

Illustrative list of questions (patent systems)	YES	NO	NA
<i>Is there any basis for denying a patent on an invention consisting of an entire plant or animal?</i>	17	6	1
<i>Does the patent system exclude entire plants/animals as inventions?</i>	2	13	9
<i>Is it possible to obtain a patent claim that is not limited to a specific plant/animal variety;</i> <i>expressly limited to a plant or animal variety;</i> <i>expressly limited to a group of plants or animals.</i>	13 9 12	5 11 3	6 4 9
<i>Is it possible to obtain a patent on a micro-organism?</i>	23		1
<i>Is it possible to obtain a patent on an essentially biological process?</i>	5	17	2
<i>Is it possible to obtain a patent for subject matter that is identical to that found in nature?</i>	1	17	6



TRIPS Council's Information-gathering Exercise under Art. 27.3(b) (3)

Illustrative list of questions: plant varieties	YES	NO	NA
<i>Does national law provide for a sui generis form?</i>	22	2	
<i>Does the form conform to standards defined in UPOV 1991 or 1978</i>	17 (91)	5 (78)	2
<i>Is the prior authorization of the right holder required in the following cases</i>			
<i>1. for research purpose or to develop new varieties;</i>		22	2
<i>2. to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics;</i>	13	8	3
<i>3. a farmer to harvest seed from his planting of a protected variety legitimately obtained, store that seed, and replant that seed on the farmer's land;</i>	1	20	3
<i>4. If prior authorization is not required, is remuneration to the right holder required?</i>	7	12	5



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Review of the Provisions of Art. 27.3(b)

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- Two general issues under the review of the provisions of Article 27.3(b)
 - Issues relating to the patent provisions of Article 27.3(b)
 - Issues relating to the *sui generis* protection of plant varieties
 - The Secretariat's summary note IP/C/W/369/Rev.1



Review of Art. 27.3(b): Issues Relating to the Patent Provisions of Art.27.3(b) (1)

- The case for providing patent protection for plant and animal inventions
 - To promote private sector investment in inventive activities
 - To facilitate the transfer of technology
 - To facilitate the operation of laws designed to protect public morality, health and environment
 - The case against providing patent protection for plant and animal inventions
 - Access to, the cost, re-use and exchange of seeds by farmers
 - The granting of bad patents
 - The interest of the countries and communities that supply the underlying genetic material and traditional knowledge
-



Review of Art. 27.3(b): Issues Relating to the Patent Provisions of Art. 27.3(b) (2)

- Suggestions made for what action might be taken by the WTO
 - To remove exceptions to patentability provided for in Article 27.3(b)
 - To leave Article 27.3(b) as it is
 - To clarify certain terms in Article 27.3(b), i.e.
 - Plants, animals, and microorganisms
 - Three criteria for patentability
 - Ethical exceptions
 - To amend or clarify Article 27.3(b) to prohibit the patenting of life forms
 - Bolivian submission of 24 Feb. 2010

Tissue
 collection of interconnected **cells**
 performing a similar function within an organism

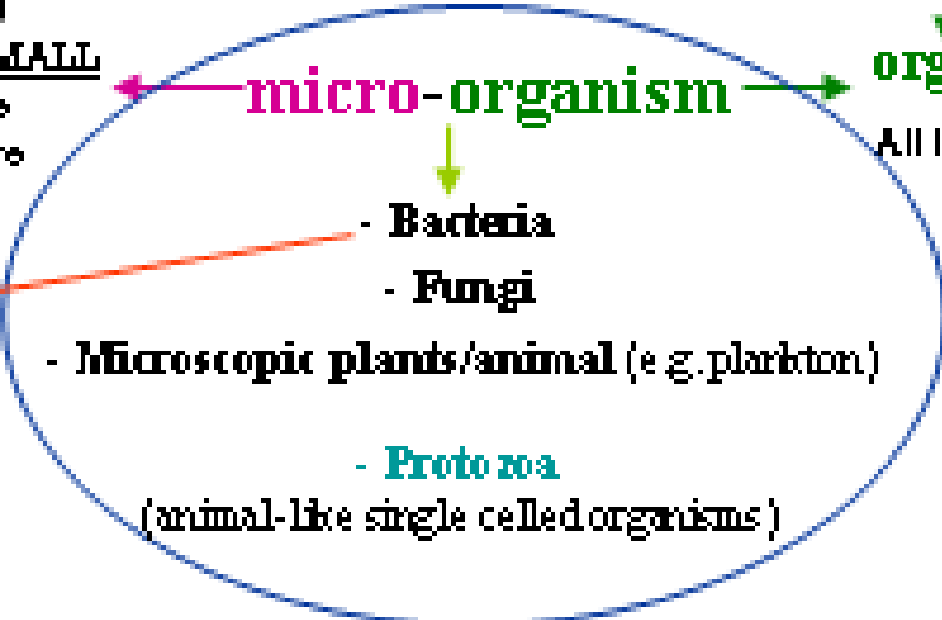
structural & functional
 unit of all **living organisms**:
cell

one **cell** many **cells**
 bacteria human

micro: too **SMALL**
 to be seen by the
 naked human eye

micro-organism

organism
 All living thing



Parasitology
Microbiology
 (visible to naked eyes)

Insect
 (not seen by
 naked eyes)

Viruses
 Non-living

Hybridoma
 Non-living

Enzymes
 Proenzymes
Protein





Review of Art. 27.3(b): Issues Relating to the *Sui Generis* Protection (1)

- The case for providing protection for plant varieties
 - To encourage development of new technological solutions in the field of agriculture
- The case against providing protection for plant varieties
 - Concerns relating to food security, health, rural development and equity for local communities whose traditional knowledge systems have produced staple varieties

Review of Art. 27.3(b): Issues Relating to the *Sui Generis* Protection (2)

- Does TRIPS strike the right balance
 - Leave Article 27.3(b) as it is
 - While preserving the flexibility in Art. 27.3(b), clarification of the term “an effective *sui generis* system”
 - To make reference to the UPOV Convention: UPOV 1991 vs. UPOV 1978
 - Farmers’ exceptions to plant breeders’ rights
 - Farmers’ rights (landraces)
 - Article 9 of FAO International Treaty on Plant Genetic Resources for Food and Agriculture
 - To spell out the detail of what is “effective”

Review of Art. 27.3(b): Issues Relating to the *Sui Generis* Protection (3)

- What constitutes an effective sui generis systems?
 - According to some members, the basic features must include appropriate coverage of
 - Subject matter of protection
 - Conditions for protection
 - Right holders
 - Exceptions to the rights conferred
 - Farmers' privilege
 - Duration of rights
 - Procedural requirements
 - Enforcement of rights
 - According to others, this is not required by TRIPS



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Protection of TK and Folklore



Protection of Traditional Knowledge and Folklore (1)

- The need for international action on the protection of traditional knowledge and folklore
- The Secretariat's summary note IP/C/W/370/Rev.1



Protection of Traditional Knowledge and Folklore (2)

- Little debate on substance in the TRIPS Council
 - No specific provisions in TRIPS
 - Members can protect TK under existing IPRs, where appropriate
 - Can introduce *sui generis* law to the protection of TK
 - Can implement CBD, provided there is no conflict with TRIPS
 - Article 8(j) of CBD: to respect, preserve, maintain knowledge, innovations as practices of indigenous and local communities and encourage the equitable sharing of benefits



Protection of Traditional Knowledge and Folklore (3)

- WIPO vs. WTO – some arguments
 - WIPO
 - On-going work in WIPO's Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore
 - Lack of clarification of the definition of traditional knowledge, the objectives of protection and modalities
 - More expertise in WIPO
 - WTO
 - WTO has its own mandate and time-frame under paragraphs 12-19 of the Doha Declaration;
 - Any conclusions reached at the WIPO will not automatically become applicable in the WTO;
 - WTO has its unique way of functioning: DSB
 - WIPO Assembly's resolution in 2003: WIPO is not the sole forum for this issue.



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Protection of Traditional knowledge and Folklore (4)

Sui generis system

- African Group's Draft Decision not discussed
 - Definition of traditional knowledge?
 - Owners and beneficiaries?
 - How to ensure benefit-sharing?
 - Objective of protection: preservation or commercialization?
 - Type, scope and conditions of protection?
 - Nature of rights, acquisition, enforcement?
 - Term of protection: permanent or not?
 - Cultural/customary law dimension?



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