



## **Topic 8**

# **The relationship between IP and access to and benefit-sharing in genetic resources**

Practical Workshop for Indigenous Peoples and Local Communities on  
Intellectual Property and Traditional Knowledge

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# What are genetic resources?

- “Genetic material of actual or potential value”
- “Genetic material” = “any material of plant, animal, microbial or other origin containing functional units of heredity”
  - See Convention on Biological Diversity, 1992
- Ex: medicinal plants, traditional crops, animal breeds

# International landscape on GRs

- Convention on Biological Diversity, 1992
- FAO International Treaty on Plant Genetic Resources for Food and Agriculture, 2001
- Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, 2002
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, 2010

# Convention on Biological Diversity, 1992

- International agreement with three objectives
  - Conservation of biological diversity
  - Sustainable use of its components
  - Fair and equitable sharing of benefits arising from the use of GRs
- **Biological diversity** means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems
- First international legally binding instrument that adopted the concept of ABS

# Access and benefit-sharing (ABS)

- A mechanism that regulates the exchange of a given resource between certain actors
- In the context of biological diversity, ABS regulates exchanges of genetic material between a legitimate holder and a subsequent user of GRs
- CBD laid down the broad principles that countries are to respect when requesting and granting each other access to their GRs
- Benefits that may arise from the use of such GRs should be shared in fair and equitable way with the country granting access

# FAO International Treaty on Plant Genetic Resources for Food and Agriculture, 2001

- Limited to plant GRs
- **Goal:** achieving global food security through the conservation and sustainable use of crop diversity
- Regulates exchange of a number of important food crops and facilitates the access to crop varieties and their components for agricultural research and breeding of new varieties
- **Multilateral System of Access and Benefit-Sharing** global pool of a number of the most important crop GRs for food security, shared and managed jointly by all countries that adhere to the Treaty

# Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, 2002

- Voluntary Guidelines
  
- Aim at assisting governments and other stakeholders
  - in developing an overall ABS strategy
  - in identifying the steps involved in the process of obtaining access to GRs and benefit-sharing
  - when establishing legislative, administrative and policy measures on ABS
  - when negotiating contractual arrangements for ABS

# Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, 2010

- International treaty adopted under the auspices of the CBD in 2010
- Entered into force on October 12, 2014
- **Objective:** the fair and equitable sharing of benefits arising from the utilization of GRs
- **Scope:** GRs and TKA, as well as the benefits arising from their utilization
- Sets out **core obligations** to take measures in relation to
  - Access to GRs
  - Benefit-sharing
  - Compliance



- GRs are **subject to regulations on access and benefit-sharing** set by:
  - The Convention on Biological Diversity (CBD)
  - The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD (Nagoya Protocol)
  - The International Treaty on Genetic Resources for Food and Agriculture (ITPGRFA) of the FAO

As implemented by regional and national systems

# Intellectual property and genetic resources

- Genetic resources, as encountered in nature, are not “intellectual property”
- They are not creations of the human mind and cannot be directly protected as IP

WHERE DOES IP FIT IN?

# Two IP-related questions/issues

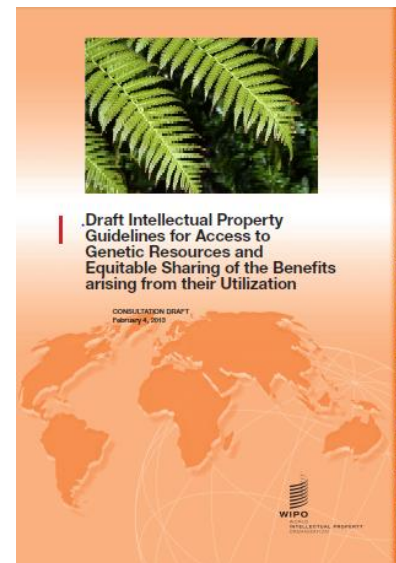
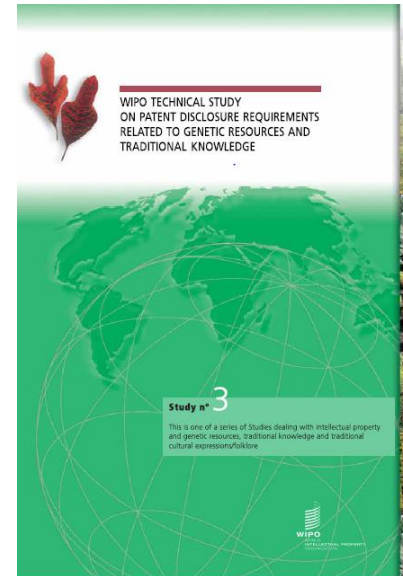
- Inventions based on or derived from GRs may be patentable (or subject to other forms of IP rights).
  - Preventing the grant of erroneous patents over GRs that do not fulfill the requirements of novelty and non-obviousness
- Using the patent/IP system to ensure and track compliance with ABS systems in national laws established pursuant to the CBD, Nagoya, FAO Treaty

# IP issues associated with GRs → Proposed responses/solutions

- prevention of erroneously granted patents
- ensuring and tracking compliance with ABS systems
- databases/information systems, information exchange, patent examination guidelines
- mandatory disclosure requirement, i.e. to make it mandatory for patent applications to show the source of origin of GRs, as well as evidence of PIC and a benefit-sharing agreement
- and/or managing patent/IP rights through contract (IP clauses in mutually-agreed terms)

# What has been done in WIPO so far?

- Technical analyses of the proposed mandatory disclosure requirement
- Draft Intellectual Property Guidelines for Access to Genetic Resources and Equitable Sharing of the Benefits arising from their Utilization
- Improved patent search and examination tools
- Draft patent examination guidelines



# Database of contractual practices

<http://www.wipo.int/tk/en/databases/contracts/>

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## Biodiversity-related Access and Benefit-sharing Agreements

Database of actual and model biodiversity-related access and benefit-sharing agreements and related information, with particular emphasis on the intellectual property aspects of such agreements.

The database is a work in progress. Interested parties are invited to contribute by completing our questionnaire [PDF](#) [DOC](#) and/or by [contacting us](#).

Contractual clauses search | Full text search | List of all contracts

OR (at least one of the specified words) Search Reset

### Intellectual Property Related Clauses

- Intellectual Property (general)
- Patents
- Distinctive Signs
- Plant Breeders' Rights
- Trade Secrets
- Copyright and Related Rights
- Ongoing Traditional and Customary Use

### Other Clauses

- Dispute Resolution
- Definitions
- Ownership
- Confidentiality
- Transfer to Third Parties
- Monetary Benefit-Sharing
- Non-monetary Benefit-Sharing

**Related links**

- Genetic resources
- Consultations on genetic resources

# CURRENT STATE OF THE NEGOTIATIONS ON GRS

# Structure of the Consolidated Documents Relating to Intellectual Property and Genetic Resources

## Rev. 2

List of terms

[Preamble]

Policy objective[s]

[Article 1] Subject matter of instrument

[Article 2] Scope of instrument

[Article 3] [Disclosure requirements]

[Article 4] [Exceptions and limitations]

[Article 5] [Relationships with [PCT] and [PLT]]

[Article 6] Sanctions and remedies

[Article 7] [No new disclosure requirement]

Defensive measures

[Article 8] [Due diligence]

[Article 9] Prevention of the erroneous grant of patents and voluntary codes of conduct

Database search systems

WIPO portal site

[Article 10] Relationship with international agreements

[Article 11] International cooperation

[Article 12] Transboundary cooperation

[Article 13] Technical assistance, cooperation and capacity building



# Key considerations of the draft text on GRs

- What should be the **policy objectives**?
- Should there be a **disclosure requirement**?
- Should there be provision for **defensive measures**?

# Policy objectives

- One main objective
  - Prevent the misappropriation of GRs
- Three sub-objectives
  - Ensure IP/patent offices have access to appropriate information to prevent the grant of erroneous patent/IP rights
  - Enhance transparency in IP/patent and ABS system
  - Ensure/promote/facilitate complementarity/mutual supportiveness with international agreements relating to the protection of GRs

# Disclosure protection

- Key normative issue
- 5 articles
  - [Article 3] [Disclosure requirements]
  - [Article 4] [Exceptions and limitations]
  - [Article 5] [Relationships with [PCT] and [PLT]]
  - [Article 6] Sanctions and remedies
  - [Article 7] [No new disclosure requirement]

**[ARTICLE 3]**  
**[DISCLOSURE REQUIREMENT]**

3.1 Where the [subject matter] [claimed invention] within a [IP Rights] [patent] application [includes utilization of] [is directly based on] [is consciously derived from the] genetic resources [their derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources] each Party shall/should require applicants to:

- (a) Disclose the [country of origin [and]] [or if unknown,] source of the genetic resources, [their derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources].
- (b) [Provide relevant information, as required by the national law of the [IP] [patent] office, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]
- (c) If the source and/or country of origin is not known, a declaration to that effect.

3.2 The disclosure requirement [shall/should] [does] not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure. [But [IP] [patent] offices are required to provide effective guidance to [IP] [patent] applicants on how to meet disclosure requirements, and to provide an opportunity for applicants to obtain from [IP] [patent] offices a positive decision that disclosure requirements have been met.]

3.3 A simple notification procedure shall/should be introduced by the [patent] [IP] offices that receive a declaration. [It would be adequate to identify in particular the Clearing House Mechanism of the CBD/ITPGRFA as the central body to which the [IP] [patent] offices shall/should send the available information.]

3.4 [Each Party shall/should make the information disclosed publically available at the time of publication.]

3.5 [Genetic resources and [their derivatives] as found in nature or isolated therefrom shall/should not be considered as [inventions] [IP] and therefore no [IP] [patent] rights shall/should be granted.]]

# Key questions on disclosure

- What should be the subject matter of disclosure? (GRs, but also derivatives? ATK?)
- What should trigger disclosure?
- What should be the content of the disclosure? (origin/source, information on compliance with ABS requirements?)
- What should be the nature of obligation to disclose? (mandatory?)
- Should IP/patent offices have to verify the content of disclosure?

- **Should there be exclusions from disclosure?** (for example, all GRs acquired/accessed before entry into force of the CBD)
- **What should be the consequence of non-compliance?** (dismissal or no further processing of a pending application; nullity or unenforceability of granted patent; administrative or criminal sanctions outside of the patent system without effect on any granted patent, revocation?)
- **Should liability be strict?**
- **How would the requirement be implemented, verified and monitored?** (for example through PCT/PLT?)

# Defensive measures

- Part on defensive measures contains 4 provisions
  - [Article 8] [Due diligence]
  - [Article 9] [Prevention of the erroneous grant of patents and voluntary codes of conduct]
  - Database search systems
  - WIPO portal site

# Prevention of the erroneous grant of patents and voluntary codes of conduct

Member States shall provide measures to:

- Prevent patents from being granted erroneously with regard to claimed inventions that include GRs where those GRs
  - Anticipate a claimed invention (no novelty)
  - Obviate a claimed invention (obvious or no inventive step)
  
- Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases of genetic resources



## ■ Database search systems

- Members encouraged to facilitate the establishment of databases of GRs

  - Minimum standards and structure of content

  - Safeguards

  - Access

## ■ WIPO portal site

- Database search system that would link databases of WIPO Member States

What do you think are some of the important issues that need to be considered when establishing a database or information system?

# Issues to consider on databases

- Who should have responsibility for compiling and maintaining the databases?
- Should there be minimum standards to harmonize structure and content?
- To whom should the databases be accessible?
- What should be the content of the databases?
- In what form should the content be expressed?
- Should there be accompanying guidelines?

Thank you!

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