

# No. 10

## Intellectual Property and Genetic Resources

### Introduction

Genetic resources (GRs) are defined in the Convention on Biological Diversity, 1992 (CBD) as genetic material of plant, animal, microbial or other origin containing functional units of heredity that has actual or potential value. Examples include medicinal plants, agricultural crops and animal breeds. Some GRs are linked to traditional knowledge (TK) and traditional practices through their use and conservation by indigenous peoples and local communities, often over generations, and through their widespread use in modern scientific research. For example, TK can provide researchers with leads to isolate valuable active compounds for medicines and other products, which can be conducive to eventual patentable inventions.

GRs themselves, as encountered in nature, are not intellectual property (IP). They are not creations of the human mind and thus cannot be directly protected as IP. However, inventions based on or developed using GRs (and associated TK) are eligible for protection through the IP system, either through a patent or, in the case of research and breeding activities that can lead to the creation of new plant varieties, by a *sui generis* system that regulates plant breeders' rights.

GRs are subject to access and benefit-sharing (ABS) regulations, in particular within the international legal and policy framework defined by the CBD and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol), as well as by the International Treaty on Plant Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization (the International Treaty).

The **CBD** is the first international agreement that addresses ABS in its objectives and provisions. It recognizes the sovereign rights of States over their natural resources and affirms the authority governments have, subject to their national legislation, to determine access to GRs.

The **Nagoya Protocol** is a supplementary agreement to the CBD. It sets out the rules and mechanisms for ABS and provides a legal framework for the effective implementation of the fair and equitable sharing of benefits arising out of the utilization of GRs.

The **International Treaty**, which is limited to plant GRs for food and agriculture, regulates the exchange of a number of important food crops, and facilitates access to crop varieties and their components for agricultural research and breeding of new varieties.

## Intellectual Property Issues

While WIPO does not address the regulation of ABS of GRs, there are IP issues directly associated with GRs, and in considering these issues, WIPO's work complements the framework provided by the CBD, the Nagoya Protocol and the International Treaty. IP issues related to GRs under discussion in WIPO include:

- **The prevention of erroneous patents.** Inventions based on or developed using GRs may be patentable. A number of WIPO Member States have adopted policies aimed at the defensive protection of GRs, to prevent erroneous patents being granted over inventions based on or developed using GRs and associated TK that do not fulfill patentability requirements such as novelty and inventiveness. The defensive protection of GRs can involve the development and implementation of a range of legal and practical mechanisms, such as databases and other information systems on GRs and associated TK to help patent examiners find relevant prior art and avoid the granting of erroneous patents. Patent disclosure requirements may also address this issue.
- **The consistency and synergy between the IP system and ABS systems.** A key IP issue in the context of ABS consists in examining whether, and to what extent, the IP system should be used to ensure and track compliance by users of GRs with national ABS systems established pursuant to the CBD, the Nagoya Protocol and the International Treaty. WIPO Member States are considering whether, and to what extent, the IP system should be used to support implementation of obligations related to prior informed consent, mutually agreed terms and fair and equitable benefit-sharing that are provided for by these ABS systems. One of the options under discussion is to develop mandatory disclosure requirements that would oblige patent applicants to show the source or origin of GRs, as well as evidence of prior informed consent and a benefit-sharing agreement, if they are required by the provider country.

Negotiations on an international legal instrument on IP issues related to GRs are taking place in the **WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)**. The IGC is currently considering a Consolidated Document Relating to Intellectual Property and Genetic Resources.

## Solutions or Mechanisms

A number of solutions or mechanisms have been developed in response to these IP issues. They include the use of databases and information systems, the development of new patent disclosure requirements related to GRs and associated TK, the management of IP issues in ABS agreements, the preparation of guidelines or recommendations on defensive protection and the improvement of methods of classification, search and examination of patent applications. These solutions or mechanisms are not contradictory and can be implemented in a mutually supportive way. They will be examined, in turn, in the following paragraphs.

### Databases and information systems

The development of information tools and databases in the field of GRs can be a valuable mechanism to address the problem of erroneous patents. Databases can help increase the likelihood that relevant information about GRs is available to patent-granting authorities for the substantive examination of patent applications, and that this information can be located and accessed, when needed, in the patenting process.

GRs databases can compile and reference a wide range of information and materials, including, for example, GRs, associated TK, derivatives, known uses of GRs and relevant scientific articles. Their status can be formal or informal and they can be held and compiled by States, research institutions or indigenous peoples and local communities. Some important issues that need to be considered with respect to the development of databases include, in particular, the responsibility for compiling and maintaining the database; the cost of setting up and operating the database; the structure and content of the database; the form in which that content would be expressed; its interoperability with other databases both nationally and internationally; a determination of the category of people authorized to access the content of the database; the type of protection afforded to the information included in the database and the management of the rights pertaining to the database.

## Patent disclosure requirements

“Disclosure” is a requirement in patent applications according to which an invention has to be disclosed in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. In the context of GRs, “disclosure requirements” refer to provisions which require patent applicants to include as part of the patent application several additional categories of information, such as the source or origin of GRs, as well as evidence of prior informed consent and a benefit-sharing agreement.

A number of countries have adopted or are in the process of adopting some form of patent disclosure requirements related to GRs and associated TK. These disclosure requirements can have the dual function to provide patent examiners with relevant information to make informed decisions on whether patentability criteria of novelty and inventiveness are met, and to complement and support ABS systems in national legislations, in particular by helping track compliance with those systems.

Some important issues that need to be considered with respect to the adoption of a disclosure requirement include a decision on the type of information that should be disclosed; the triggers of disclosure; the nature of the disclosure (mandatory or voluntary); any exceptions or limitations that would apply; the consequence(s) of non-compliance with the requirement such as sanctions and remedies, and a determination of how the requirement would be implemented, verified and monitored.

## The management of IP issues in ABS agreements

A primary means of giving effect to the equitable sharing of benefits arising from the access to and use of GRs is through mutually agreed terms, or contracts, which are to be agreed between provider and user of GRs.

Within ABS agreements, the specific arrangements made for IP management can influence the overall results of access to GRs. Careful management of IP issues during the negotiation, development and drafting of an ABS agreement can be important in ensuring that an access agreement actually creates benefits, and that benefits are shared equitably, respecting the interests and concerns of the resource providers. IP issues that can be determined in agreements include the entitlement to seek IP rights in inventions and other results of research using the resources; the ownership and licensing of any such derivative IP; the responsibility for maintaining and exercising IP rights; the arrangements for distributing any financial or other benefits resulting from this derivative IP, and the requirement for the recipient of the resource to report on any IP that is applied for.

WIPO has developed and maintains a Database of Biodiversity-related Access and Benefit-sharing Agreements, which contains actual and model biodiversity-related ABS agreements and related information, with particular emphasis on IP aspects of such agreements. It has also prepared draft Intellectual Property Guidelines for Access to Genetic Resources and Equitable Sharing of the Benefits arising from their Utilization that illustrate the practical IP issues that providers and recipients are likely to face when negotiating an agreement, thereby enhancing the information available to stakeholders assessing their IP options.

## Guidelines and recommendations

The preparation and making available of guidelines and other recommendations on defensive protection can help guide patent authorities, for example, when examining GRs-related patent applications, so as to decrease the likelihood of the grant of patents in respect of inventions that do not fulfill patentability requirements.

## Improved classification, search and examination

A practical aspect of efforts to avoid erroneous patents is to ensure that relevant information is available to search authorities and patent examiners, and that it is readily searchable, such as through being appropriately indexed or classified, so that it is likely to be found in a search for relevant prior art.

To help patent examiners find relevant prior art when they examine applications which claim inventions based on, or derived from, GRs and associated TK, WIPO has improved its own search tools and patent classification systems.

## Further Information

Database of Biodiversity-related Access and Benefit-sharing Agreements

[www.wipo.int/tk/en/databases/contracts/](http://www.wipo.int/tk/en/databases/contracts/)

Database of Legislative Texts relevant to Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources

[www.wipo.int/tk/en/databases/tklaws/](http://www.wipo.int/tk/en/databases/tklaws/)

Disclosure requirements table [www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic\\_resources\\_disclosure.pdf](http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf)

Draft Intellectual Property Guidelines for Access to Genetic Resources and Equitable Sharing of the Benefits arising from their Utilization [www.wipo.int/export/sites/www/tk/en/resources/pdf/redrafted\\_guidelines.pdf](http://www.wipo.int/export/sites/www/tk/en/resources/pdf/redrafted_guidelines.pdf)

WIPO Technical study on patent disclosure requirements related to genetic resources and traditional knowledge [www.wipo.int/edocs/pubdocs/en/tk/786/wipo\\_pub\\_786.pdf](http://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf)

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