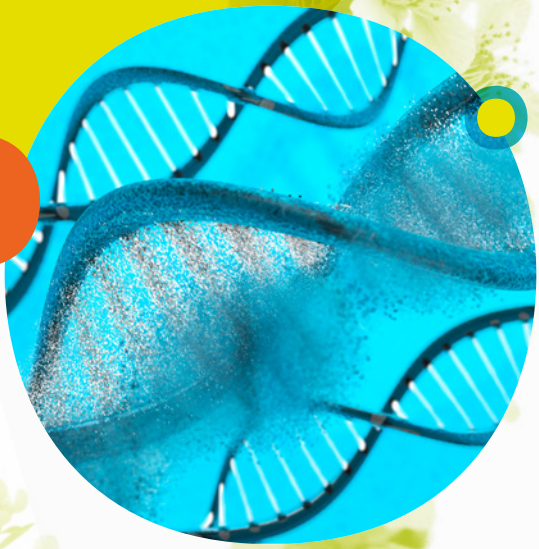
Background Brief
No. 10

Intellectual Property and Genetic Resources



WIPO

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, and do not include "human genetic resources". Examples include medicinal plants, agricultural crops and animal breeds. Some GRs are linked to traditional knowledge (TK) through their use and conservation by Indigenous Peoples as well as local communities, often over generations, and through their widespread use in modern scientific research. Genetic material, according to the CBD, is any material of plant, animal, microbial or other origin containing functional units of heredity. Due to recent technological advances, genetic material can be described with increasing ease and speed through digital sequence information (DSI). The process by which GR samples are described to be identified or differentiated by their genetics or appearance is referred to as "characterization". GRs are one type of biological resource, which, according to the CBD, include GRs, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

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 GRs (and associated TK) are patentable, or eligible for protection through other IP systems.

GRs are subject to access and benefit-sharing (ABS) regulations, in particular within the international regime on ABS. The international regime is constituted of the CBD, the 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 complementary instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture (the International Treaty), the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization and the Pandemic Influenza Preparedness (PIP) Framework of the World Health Organization (WHO). In 2023, the Agreement on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction was adopted under the United Nations Convention on the Law of the Sea.

The management of IP issues in ABS agreements

While WIPO does not address the regulation of ABS of GRs as such, there are IP issues directly associated with GRs (and associated TK), and in considering these issues, WIPO's work complements the framework provided by the CBD, the Nagoya Protocol, the International Treaty, the PIP Framework and other elements of the international regime on ABS. Within ABS agreements, the specific arrangements made for IP management can influence the overall results of access to GRs (and associated TK). Careful management of IP issues during the negotiation, development and drafting of an ABS agreement can be important in ensuring that the agreement creates benefits and that they are shared equitably, respecting the interests and concerns of the resource providers. WIPO has developed and maintains an online collection of genetic resource agreements, which contains ABS agreements, licensing agreements and related information, with particular emphasis on the IP aspects of such agreements. Based on the online collection, WIPO has also prepared a *Guide on Intellectual Property Issues in Access and Benefit-sharing Agreements*, which illustrates the practical IP issues that providers and recipients are likely to face when negotiating an agreement, thereby enhancing the information available to GR stakeholders in assessing their IP options.

Intellectual property issues

One of the IP issues related to GRs under discussion in WIPO is the prevention of erroneous patents. Inventions based on GRs and associated TK may be patentable. A number of WIPO Member States have adopted policies to prevent patents from being granted erroneously for inventions based on GRs and associated TK that do not fulfill patentability requirements such as novelty, inventiveness or industrial applicability. The defensive protection of GRs and associated TK 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.

WIPO Treaty on GRs and associated TK

WIPO Member States adopted, by consensus, a historic new WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (the Treaty) on May 24, 2024. This is the first WIPO Treaty to address the interface between IP, GRs and associated TK and the first WIPO Treaty to include provisions specifically for Indigenous Peoples as well as local communities.

The Treaty aims to enhance the efficacy, transparency and quality of the patent system with regard to GRs and associated TK, and prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to GRs and associated TK.

The Treaty will come into force three months after there have been 15 ratifications and accessions.

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 and associated TK, "disclosure requirements" refer to provisions that 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. The WIPO publication *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* offers practical and empirical information about such requirements for policy makers and other stakeholders.

The new WIPO Treaty establishes a mandatory patent disclosure requirement – this requires patent applicants to disclose the country of origin of the GRs and/or the Indigenous Peoples or local community providing the associated TK, if the claimed inventions are based on GRs and/or associated TK. If such information is unknown, the source of the GRs or associated TK should be disclosed. If none of the above mentioned information is known, the patent applicant would be required to declare so.

Patent offices should provide certain guidance, though they would have no obligation to verify the authenticity of the disclosure. A failure to disclose the required information would be subject to appropriate, effective, and proportionate measures. Patent applicants would have the opportunity to rectify a failure to disclose the required information unless there has been fraudulent conduct or intent. Where there has been fraudulent intent in regard to the disclosure requirement, post grant sanctions or remedies may be provided for. Fraud aside, no party to the Treaty should revoke, invalidate, or render unenforceable a patent solely on the basis of an applicant's failure to disclose the required information. Subject to existing national laws on disclosure, the Treaty includes a non-retroactivity clause, i.e. no obligations of the Treaty should be imposed in relation to patent applications filed prior to the entry into force of this Treaty.

Information systems

The development of information tools and databases in the field of GRs and associated TK has been identified as one approach to address the problem of erroneous patents. Databases can help increase the likelihood that relevant information about GRs and associated TK 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. Databases can compile and reference a wide range of information and materials, including, for example, information about GRs, associated TK, known uses of GRs and relevant scientific compilations. WIPO maintains existing databases of patent literature, such as Patentscope, that include sequence listings of GRs, and has developed international standards on how such GRs sequence listings should be described and exchanged within patent information systems.

The Treaty suggests the establishment of information systems (such as databases) of genetic resources and associated TK, in consultation, where applicable, with Indigenous Peoples and local communities, and other stakeholders, taking into account their national circumstances. The information systems should be made accessible to patent offices for the search and examination of patent applications, with appropriate safeguards developed in consultation, where applicable, with Indigenous Peoples and local communities, and other stakeholders. One or more technical working groups may be established to address any relevant matters, such as accessibility to patent offices.

Conclusion

WIPO is ready to support Member States, on request, in relation to the ratification/accession and implementation of the Treaty.

Inventions based on GRs have constituted a distinctive and unique category of subject matter for IP protection since the emergence of modern biotechnology and modern plant breeding. Technology, as it relates to the living world, is changing rapidly, and understanding its legal, policy and scientific implications is becoming a more complex challenge. WIPO continues to provide accurate IP information, technical assistance, training and capacity building to understand the classical and emerging issues at the interfaces between GRs and IP. Further information is available on the WIPO website.

Further information

WIPO Guide to IP Issues in Access and Benefit-sharing Agreements
www.wipo.int/publications/en/details.jsp?id=4329

Biodiversity-related Access and Benefit-sharing Agreements
www.wipo.int/en/web/traditional-knowledge/databases/contracts/index

Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge,
www.wipo.int/publications/en/details.jsp?id=4498

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC),
www.wipo.int/en/web/igc

A series of Background Briefs prepared by WIPO on various topics,
www.wipo.int/publications/en/series/index.jsp?id=144

WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, www.wipo.int/en/web/traditional-knowledge/wipo-treaty-on-ip-gr-and-associated-tk

More WIPO resources are available at
www.wipo.int/en/web/traditional-knowledge/global-reference

© WIPO, 2024 / Attribution 4.0 International (CC BY 4.0) / The CC license does not apply to non-WIPO content in this publication.
Cover: fatido and Kamada Kaori / iStock / Getty Images Plus via Getty Images / WIPO Reference RN2023-5.10EN; DOI: 10.34667/tind.47919

wipo.int

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION