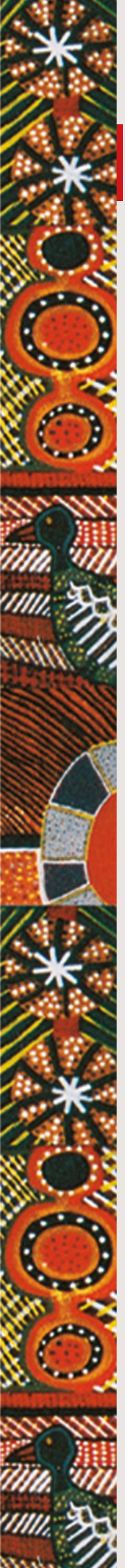

No. 10

Intellectual Property and Genetic Resources

Background Brief

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. 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 resources, which, according to the CBD, include genetic resources, 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 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. Some types of DSI of GRs may also be eligible for copyright protection. Finally, some GRs and some DSI of GRs may be eligible for protection as undisclosed information under certain circumstances.

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).

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Intellectual property issues

While WIPO does not address the regulation of ABS of GRs as such, 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, the International Treaty, the PIP Framework and other elements of the international regime on ABS. 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, which is 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, inventiveness or industrial applicability. 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. Proposed new patent disclosure requirements may also address this issue (see below).

The consistency and synergy between the IP system and ABS systems. One IP issue that has been raised in the context of ABS is whether, and to what extent, the IP system should be used to ensure compliance by users of GRs with national ABS systems established pursuant to components of the international regime. WIPO Member States are considering whether, and to what extent, the IP system may 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 a new disclosure requirement 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.

A number of approaches have been developed in response to these IP issues. They include the management of IP issues in ABS agreements and frameworks, the use of databases and information systems and the development of new patent disclosure requirements related to GRs and associated TK. These approaches are not contradictory and can be implemented in a mutually supportive way.

The management of IP issues in ABS agreements

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. 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.

Databases and information systems

The development of information tools and databases in the field of GRs has been identified as one approach 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. GR 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.

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. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the WIPO Intergovernmental Committee) is negotiating such possible new requirements and 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.

New uses and emerging issues

The use of GRs for innovation has been undergoing profound transformations through the so-called "fourth industrial revolution", which is broadly defined as the transformative change in data and technology capabilities, combined with a merging of the digital, biological and physical realms. Genomics, gene editing, synthetic biology, bioinformatics, the use of artificial intelligence in the life sciences, the application of digital trust technologies to genetic and genomic data, molecular 3D printing, bio-nanotechnology and other evolving technologies, as well as their mutual convergence, are some of its most recognizable manifestations. They are being deployed at an unprecedented rate to solve a myriad of technical problems, with practical uses and implications in almost all fields of the life sciences and beyond which use and transform biological systems. These cross-cutting and knowledge intensive technological developments are unlocking and integrating potential values from living and non-living systems alike and becoming a suite of transformative tools. The convergence between biological, digital and material systems engineering is having its most noticeable impacts in industrial biotechnology, food and agriculture and the health and pharmaceuticals sectors, with new ways of breeding improved plant varieties and animal breeds, undertaking clinical diagnosis, producing personalized medical cures for diseases, treating patients, and enhancing agricultural and industrial production in general.

Ongoing processes addressing emerging uses of genetic resources and their IP relevance

Genomics, gene editing and other emerging technologies have triggered intensive discussions within international fora addressing genetic resources, such as the CBD regarding their implications for ABS, particularly in light of the adoption of the Nagoya Protocol, in the International Treaty and in the PIP Framework. Similar issues have arisen in the FAO Commission on Genetic Resources for Food and Agriculture, the UNESCO International Bioethics Committee and the WHO Expert Advisory Committee on Human Genome Editing. WIPO engages with the processes in relevant international fora and, upon request and within its mandate, provides IP-specific inputs to those processes on technical IP issues.

Synthetic biology has also become part of recent debates in these fora, as questions are raised regarding innovation policy, access to genetic resources and benefit sharing, biosafety, the precautionary principle as well as questions of morality and ordre public where wholly new genetic creations are developed, based purely on use and combination of gene sequences, from public and private databases.

Genetic engineering and the development of living modified organisms (LMOs) have been subject of extensive discussions within the CBD, which led in the early 2000s to the adoption of the Cartagena Protocol on Biosafety (2000) and later to the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress (2010). Living modified organisms are one of the multiple products and innovations that these technologies can help generate.

Patents

What is and what is not patentable in the field of these emerging technologies remains subject to going evolution in the practice of patent granting authorities. Under most patent laws, mere products of nature and discoveries, where no human innovation is involved, are not patentable. This is a widely accepted general principle. Isolation of a biological component from its natural form or its artificial transformation, changes that assumption, and administrative bodies and courts have been left to decide on patentability. In the life sciences, from the Diamond v. Chakrabarty (1980) decision by the US Supreme Court, where an otherwise naturally occurring bacteria was genetically modified and patented, to the Association for Molecular Pathology v. Myriad Genetics Inc. (2013) decision, where the Supreme Court invalidated Myriad's claims to isolated and unmodified DNA sequences, it has become clear over time that mere identification of a genetic sequence as such is not sufficient to fulfil all patentability requirements. Given the territorial nature of patents, these may be obtained in some countries and denied in others according to national laws and jurisprudence. The European Union Biotechnology Directive (1998), for instance, allows for patents on gene sequences isolated from nature. Elements isolated from the human body, including sequences and partial sequences of a gene, may be patentable under the Directive (Article 5.2).

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977) was approved as a response to the need to fully disclose patentable inventions, with regards to microorganisms and the limitations which written claims and descriptions often pose in this field of research. The term "microorganism" is not defined in the Treaty and, in practice, international depositary authorities have usually accepted all kinds of cell lines and microbiological components. Possible implications of DSI for the treaty's system of deposit of microorganisms are being explored.

Copyright

Discussions about copyright protection of sequence information can be traced back to the 1980s. However, sequence information has yet to be widely recognized as copyrightable and jurisprudence is limited. A useful analogy is illustrative: computer software programs can be protected under copyright and some limited similarities between computer algorithms and DNA sequences and their encoding functions may be drawn. This is particularly so where *de novo* "genetic creations" are being delivered. In terms of copyright requirements and principles, originality of authorship may not be arguable in the case of natural genes and genomes, however in the case of synthetic biology or recombinant DNA, truly novel, human designed sequences are written from scratch; in the case of such subject matter, no existing copyright law expressly mentions genomic sequence data or other characterization data of genetic resources, however it has been suggested that some might fit under the "literary works" category in as much as they have an internal language that can be expressed in words, symbols and numbers as codes are deciphered and rearranged; in terms of functionality, if DNA sequence information is original, it cannot by definition infringe upon another work of authorship. Thus it has been maintained that some genetic sequence data might be protected by copyright to the extent that nucleotide sequences are not dictated by functionality (they are non-utilitarian); finally, many national laws would allow certain exceptions for some purposes, such as teaching, scholarship or research. They can take the form of general exceptions such as fair dealing or specific statutory exceptions.

Intellectual property and digital sequence information

DSI is taking an increasingly active role in management and manufacture of GR-based products and processes, and in claims of ownership of these products and processes because it is an underlying means to describe IP, for example, when nucleotide sequence listings are used to define patent claims. Therefore, two aspects regarding the interfaces between IP and DSI may be observed.

First, DSI and IP have different and increasingly diverse roles in R&D and innovation based on GRs: DSI is a component of nearly all research on GR in the biological sciences.

DSI on GR is also central to product and IP development, and expected to increase in importance especially as DSI on more kinds of organisms becomes relevant to GRs. For example, DSI is used in regulations on food safety, product labeling, and correct identification of food components, which can be important for the conservation of threatened GRs for food and agriculture. It is also used to both diagnose diseases in all forms of GRFA and to design therapeutics for treatment.

The goals of generating DSI of GRs may include to establish IP, including for licensing income. This may come from proprietary information or a mix of private and public information. For example, a genetic linkage map of *Coffea arabica L*. including sections of DNA which correlate with variations of yield, plant height and bean size in the grown plant was developed using a combination of public and proprietary databases of coffee DSI. In addition to database content, tools for accessing or using the content may be proprietary. For some GRs, private or proprietary databases that could hold critical information necessary to extract maximum value from public databases, are growing.

Second, in some aspects well-established IP principles and jurisprudence are being challenged, particularly in the area of patents and copyright as they relate to "genetics" broadly and these emerging technologies. For example, patentability requirements, scope of claims, DNA-based copyrightable works, overlaps between what may be patentable and copyrightable, *inter alia*, are some of the emerging IP-specific issues that might receive further attention.

How the WIPO Secretariat addresses these new issues in its ongoing work

As regards the work of WIPO, certain interfaces between IP and these emerging GR issues have already been addressed by WIPO's Program 4, which is the Organization's program addressing IP and GRs, traditional knowledge and traditional cultural expressions. IP issues regarding DSI which arise in the context of ABS contracts covering DSI subject matter have been described in the *WIPO Guide on IP Issues in Access and Benefit-sharing Agreements*. Additional contracts addressing IP and new issues in GRs are continuously being added to the online collection of GR contracts on which the WIPO Guide is based. Related IP issues have been identified by some delegations in the WIPO Intergovernmental Committee. WIPO has also developed standards for the presentation of nucleotide and amino acid sequence listings in patent applications, namely ST.26, which globally standardizes the way in which DSI is used in patent applications to define claims over inventions consisting of genetic sequences. Most significantly, WIPO's ongoing capacity building and training activities related to IP and GRs under Program 4 address current and emerging issues in this field. In the context of such training and capacity building, GR and IP stakeholders are provided practical, accurate and detailed IP information in order to be able to practically and proactively use the strategic opportunities emanating from these new uses of GRs. The activities aim to create a better understanding of the IP and ABS implications of the technological progress, address the IP needs of GR stakeholders in relation to the new uses, and create a practical understanding about how IP law and policy applies to these new uses of GRs so that the IP systems can be better used to promote innovation based on GRs.

Conclusion

GRs have constituted a distinctive and unique category of subject matter for IP protection since the emergence of modern biotechnology and modern plant breeding. WIPO has been addressing the distinctive IP issues that are raised by this subject matter in its Program 4 since 1998. However, as possibly in no other time in history, technology developments merging the digital, physical, and biological realm are now dramatically changing the ways in which innovation utilizes GRs. 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 therefore continues to provide accurate IP information, technical assistance, training and capacity building for GR stakeholders 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/tk/en/databases/contracts/*

Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, *www.wipo.int/publications/en/details.jsp?id=4194.*

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

A series of Background Briefs prepared by WIPO on various topics, *www.wipo.int/tk/en/resources/publications.html.*

More WIPO resources are available at *www.wipo.int/tk/en/resources/publications.html.*

World Intellectual Property Organization
34, chemin des Colombettes
P.O. Box 18
CH-1211 Geneva 20
Switzerland

Tel: +4122 338 91 11
Fax: +4122 733 54 28

To contact WIPO's External Offices
visit www.wipo.int/contact/en/

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