Intellectual Property Guide for Genetic Resources and Genetic Sequence Data

Integrated intellectual property management for genetic material and genetic sequence data

Comments may be sent by email to grtkf@wipo.int

INTELLECTUAL PROPERTY GUIDE FOR GENETIC RESOURCES AND GENETIC SEQUENCE DATA

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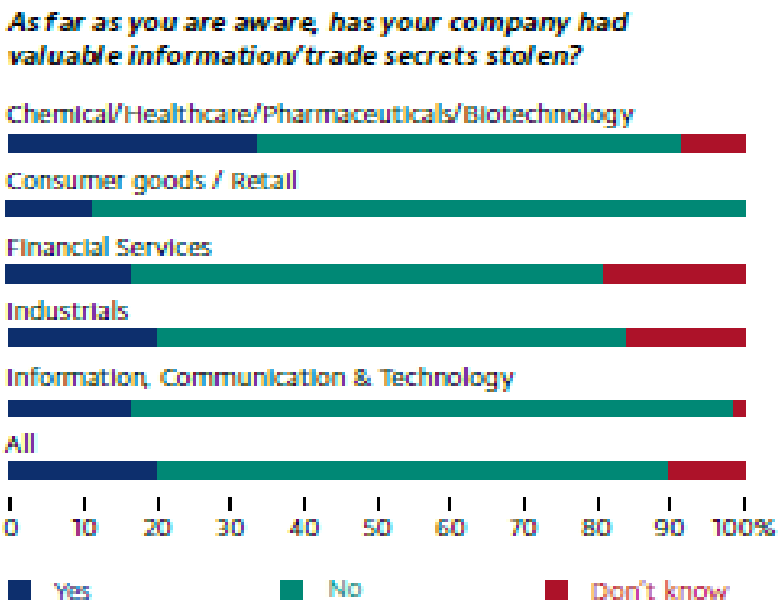
Contents

I. FOREWORD

In the context of the fourth industrial revolution, digital transformation is directly affecting the use of genetic and biological resources. In this suite of capacity building tools, the World Intellectual Property Organization's Program 4 is addressing this digital transformation by providing practical tools, services and training related to the management of intellectual property (IP) in genetic resources (GRs) and related innovations and data. WIPO's resources address the needs of all GRs stakeholders who are affected by, and proactively shaping, the digital transformation of genetic and biological resources. The aim is to assist them in responding to the new uses of GRs and to strategically manage related IP rights.

The WIPO resources are provided as a suite of practical trainings, tools and related support services for the management of IP in GRs and related innovations and data. This Guide forms part of this toolkit and addresses the needs of innovators who are innovating with GRs and GR data.

Within the data-intensive characterization and uses of GRs, IP rights play an increasing role because such uses depend on, and generate, intangibles, such as data, scientific information and inventions, which drive GR-related innovation. IP is a key incentive for innovation, technology transfer and dissemination in the value chains utilizing GRs. Furthermore, use of IP itself in GR-based innovation is changing. Patents, trade secrets and plant variety protection are increasingly complemented with copyright, *sui generis* protection of non-original databases and regulatory data protection.



Global extent of trade secret theft in the biotech/pharma/health/chemicals sector, compared to other industrial sectors. (Source: BakerMcKenzie, 2019, p.6)

Trade secrets and preventing their misappropriation gain importance, especially – as shown in a recent study – in the chemical, health, pharmaceutical and biotechnology sectors, which primarily use GRs and related data. The same study shows that these industries have the highest percentage of entities that are considering trade secret inventories and actions against trade secret misappropriation. This Guide aims to support protecting such trade secrets and related IP rights.

In addition to the increasing relevance of GR-related IP, the intersection with neighboring areas of GR laws – in particular, access and benefits sharing – regulations are becoming more complex. While these intersections require an integrated rights management approach throughout the value chain, this Guide addresses exclusively the IP-specific dimensions of such rights management. In addition, in the context of evolving technological and regulatory frameworks the growing dematerialization of GRs in their new uses requires an increasingly integrated management of rights and obligations pertaining to GRs as well as to the related intangibles (e.g., data, know-how, traits,

inventions, molecular processes and events, varieties, etc.). There is therefore a growing practical complexity in the daily rights management which GR innovators, entrepreneurs and other stakeholders need to undertake on an ongoing basis.

This Guide addresses this practical need for integrated rights management of GRs and related data from an IP perspective. It is a practical resource for anyone who is involved in characterization, utilization, innovation and development of GRs and related innovations or data. It may be used with other elements of the toolkit on IP management of GRs and GR data. It was prepared with the continuous feedback from GRs innovators and entrepreneurs on their needs, experiences and lessons learned, when conducting practical, real-world projects on IP, GRs and related innovations or data in their institutions, companies and countries. Based on this verification in applied IP-GRs work, the Guide provides practical tips, examples, case studies and further references to assist innovators working on GRs and related innovation or data to manage their rights and to find additional resources for support. In this context, the Guide also refers to complementary elements of the wider IP-GR toolkit, including its specific tools and related support services for trade secrets, technical public disclosure, patents and licensing.

While the Guide is a practical resource for innovators and practitioners of GRs, no part of WIPO's resources, tools and services, including this Guide, provides any legal or policy advice on any aspects or issues described in them. Similarly, they do not endorse or oppose any policy approaches or positions related to the subjects discussed. They are technical resources, tools and services to address the practical needs when characterizing and developing GRs with the new characterization techniques that have become more widely accessible and used in recent years. It incorporates the contributions, both in terms of identifying IP needs and in terms of sharing lessons learned for addressing them, from many experienced experts and institutions working on GRs and IP around the world.[1] WIPO thanks all of them for their contributions.

[1] The Indonesian Agency for Agricultural Research and Development hosted several consultation workshops during the drafting phase and invested extensive resources in dedicating an expert team to the drafting of certain parts of the initial version of this Guide. Additional feedback and contributions were made by a study group of the WIPO-PRV International Training Program on IP and GRs in Support of Innovation as well as numerous guest experts from national and international companies, research institutes, gene banks and universities, who shared their valuable knowledge and experience.

II. EXECUTIVE SUMMARY

One of the key transformations of the fourth industrial revolution is the digital transformation of the use of genetic resources (GRs). This represents a shift from the classical uses of GRs (i.e. genetic material as the physical carrier of genetic information) towards the use of genetic sequence data (GSD) and other forms of GR data in their own right. These data are becoming an intangible subject matter in their own right. As this transition occurs, intellectual property (IP) becomes increasingly central to the use of GRs and GR data, including GSD. Consequently, practitioners have expressed a need for practical, legally and scientifically accurate IP information on how to manage IP during the integrated use of GRs and GR data.

This Guide addresses that need in an integrated manner in the combined use of GRs and GR data, especially GSD. However, as there is a high degree of legal and technological complexity and many, complex innovation pathways based on GRs or GR data, this Guide does not intend to replace legal advice or describe all the necessary IP considerations and the need to set several strategic foci.

Firstly, this Guide focuses on a strategic transition point: the processes that facilitate the shift from 'genetic material' as the carrier of genetic information to 'GSD' – i.e., the genomic and transcriptomic characterization that creates digital sequence data of GRs. Secondly, within GSD and other GR characterization data, the Guide focuses on genomic sequence data, specifically nucleotide sequence listings. Thirdly, the Guide focuses on rights management, particularly of IP rights, for such GRs and GR data.

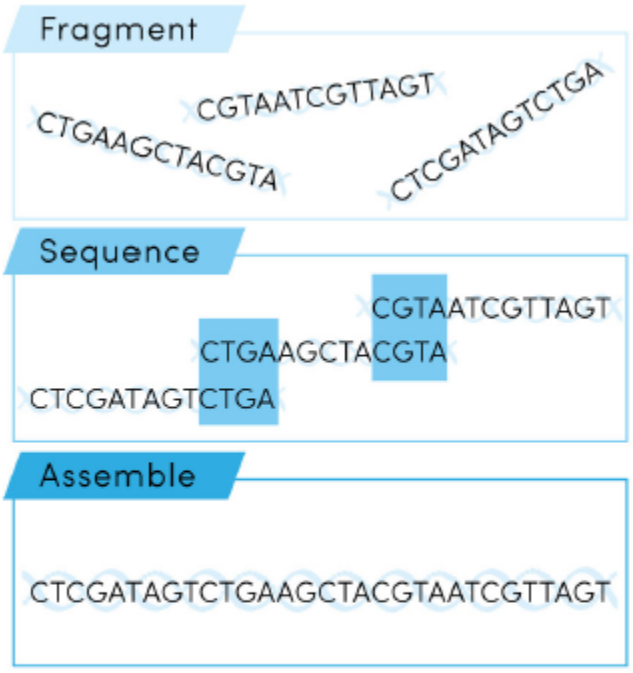
Within this focus, the Guide provides information on IP rights management related to GRs and GR data, including all relevant branches of IP law – i.e., patents, copyright, trade secrets and technological protection measures. Whereas other rights and obligations related to GRs and GR data are relevant (especially those deriving from the application of access and benefit-sharing (ABS) frameworks), the focus here is specifically and only on IP rights management. However, since the management of IP rights and ABS rights are closely connected in practice in the innovation process, it is important, especially for commercial research in the private sector, to develop and implement IP and ABS rights management strategies in an integrated and holistic manner. This Guide does not address ABS, but provides references to further information resources on relevant ABS legal frameworks and how to ensure compliance with them through effective ABS rights management.

The core of the Guide is structured in three parts: Before Characterization; During Characterization; and After Characterization (Parts II, III and IV, respectively). In a simplified narrative, the Guide covers rights management-related information regarding the relevant main branches of IP law – i.e., trade secrets, patents, copyright and certain technological protection measures. Where applicable, this information covers possible measures and strategies for both (a) avoiding infringement of third parties' IP rights, as well as (b) positive, proactive acquisition and exercise of IP rights. The Guide thus seeks to integrate the practical application of IP law to GRs and GR data into a comprehensive rights management approach for: (a) managing relevant legal encumbrances on GRs and related GR data in an integrated manner; and (b) developing a comprehensive positive rights management strategy for acquiring or exercising IP rights related to GRs and GR data.

The intended audience of the Guide are practitioners who conserve, exchange, characterize, utilize, develop, improve or innovate using GRs or GR data in both the public and private sectors. The Guide is written with an emphasis on public research. For commercial settings, numerous additional market-related considerations will be necessary, which cannot be addressed in this short Guide and for which specialized legal and strategy advice should be sought. Nevertheless, active rights management for GRs and GR data is necessary also for public sector innovators working with public goods objectives, even when following an open innovation approach and not filing for IP rights.

The entire IP toolkit related to IP and GR rights management, including this Guide, is organized as a practical suite of information, tools and services for application in the characterization and use of GRs and GR data, with practical tips, examples, lessons learned, warnings, sectorial specificities, legal cautions, further resources and references to relevant products and services.

In the Annexes, the Guide also provides samples of a laboratory notebook policy, invention disclosure form and a copyright log. It also provides a link to WIPO Standard ST.26 on sequence listings.



Next generation sequencing involves determining an individual's genetic sequence in millions of short segments which are then assembled into a complete sequence.

III. INTRODUCTION

The characterization of genetic and biological resources has gone through rapid advances in recent years due to new molecular characterization techniques – such as genomic sequencing – or new and more easily accessible techniques for mapping the transcriptomes, proteomes or entire metabolomes of organisms. These new characterization techniques have been recognized as the most powerful drivers of innovation based on GRs in numerous fields and sectors of GR utilization. They are generating large amounts of biological characterization data at unprecedented speed and scale. These data themselves become the basis of novel value chains which add value at different stages of innovation processes based on original characterization data (see Fig.1.1)

In this process, the availability and application of very large data sets are also transforming innovation pathways based on GRs into increasingly data-driven innovation patterns and thereby changing the needs of innovators for maintaining legal certainty in the results of their characterization and innovation efforts.

Increasingly, these results take the form of intangible assets, such as data sets, data compilations and databases, scientific literature, traits, biological processes and molecular events, or full-fledged biotechnological inventions.

The role of IP rights becomes more and more central as innovation patterns based on GRs increasingly generate – and are based upon – such intangibles. The branches of IP law and practice that become relevant for GR-based innovation are expanding from classical industrial property rights – such as patents, trade secrets and plant variety protection – to copyright, and, where applicable, *sui generis* database protection and regulatory data protection. Trade secret protection particularly requires active attention to be recognized, continuously maintained and enforced. Moreover, for innovators, the acquisition, exercise and enforcement of these rights are increasingly enmeshed with the management of rights, obligations and compliance with neighboring legal frameworks of GRs law, particularly in ABS and a series of regulatory frameworks for market approval of the innovation products resulting from such new uses of GRs.

A. Objectives

This Guide aims to provide useful practical guidance for innovators on how to manage IP rights in an integrated process for genetic material and genetic sequence data in GR characterization and innovation initiatives. It also refers to, but does not address, related legal frameworks, in particular, ABS frameworks applicable to GRs involved in the characterization and innovation process.

The objective of the Guide is to give the reader a process framework and information resource for practical and strategic rights management during GR characterization and innovation work, without giving legal advice on the specifics of research, characterization or innovation projects. It is important to obtain specific, professional legal advice from other sources and to recognize what this Guide is not.

The aim of this Guide is to be technology neutral and it does not privilege any one system, protocol or technological tool over another in its description of the legal issues that arise during GR characterization and GR data utilization. It addresses not the technological but the legal and policy options for GR and IP management. Therefore, no assumptions are made as to the application of any technological process, neither at the characterization and sequencing stage (i.e., sequencing or genotyping technologies), nor at the GR data processing stage (i.e., specific databases, platforms, data repositories or other IT systems). Rather, it seeks to describe the application of IP law to the specific subject matter of GR data and material irrespective of current technologies used for their processing and/or generation.

B. Beneficiaries and target audience

As the fourth industrial revolution and digital transformation sweep across all GR-based sectors, they simultaneously, but differently, affect all stakeholders in their diverse functions and levels within those sectors. There are strong feedback loops between the effects, which these changes have at the different levels and locations within different sectors. Therefore, the impacts, perspectives and needs of stakeholders are different at different levels of GR and GR data ecosystems.

This Guide aims to serve innovators and stakeholders who directly characterize GRs or innovate on the basis of such resources or the resulting characterization data (especially genomic sequence data), information and knowledge, as well as compilations thereof. It pays attention to the needs of such innovators, who wish to establish distinct mechanisms, tools and systems for managing their GRs, GR data and related rights and obligations in an integrated form, such as GR and GR data platforms, repositories, gateways and databases. This may include providers, intermediaries and recipients of GRs. The potential target audience may include the entire range of stakeholders who work at the interfaces between, and with a combination of, genetic material and genomic sequence data (and other characterization data), including academic institutions, public research institutions, private sector companies, gene banks, biobanks, culture collections, botanical gardens and other ex-situ collections, government agencies, landowners, and individuals wishing to conduct research and development on GRs.

C. How to use this Guide

This Guide is written as a practical resource for GR and IP practitioners who work with the practical characterization and use of GRs, so it assumes a basic familiarity with some fundamentals of IP as well as the science and technology basics of one's GR sector and technologies, although it does not require one to be a scientist. The Guide contains supplementary information intended to offer additional information resources where legal, scientific or technological aspects are unfamiliar.

The Guide is framed around a 'before-during-after' narrative of characterization. The user is advised to read the sections sequentially from start to finish. However, it also has a modular structure and can be used as a reference book. Throughout the Guide are icons indicating the following practical elements:

Practical Tip: Action-oriented tips and tricks on IP or GR rights management.

Key Legal Issue: Pointers related to core legal choices, issues and decisions in scientific, innovation, conservation or commercial practice.

Sectorial GR Specificities: The IP needs of GR stakeholders have clear communalities across sectors, as well as sectorial specificities. Elements that identify sectorial specificities are identified with the following icons:

red: biomedical and pharmaceutical sector – sectorial specific issues in the biomedical and pharmaceutical sectors, including biological drugs such as monoclonal antibodies, interleukins and vaccines, which are substances made from living organisms and used for the prevention, diagnosis or treatment of diseases;

green: food and agriculture sector – specific issues arising in the food and agriculture sectors, including crop production and protection, plant and animal breeding, horticulture, biofuels, multipurpose crops and animal systems;

white: industrial biotechnology – specific issues arising in industrial biotechnology, including industrial enzymes, biocatalysts, microbial cell factories, industrial biological processes for the production of chemicals, food and feed, detergents, paper and pulp, textiles and bioenergy, such as biofuels;

blue: marine and aquaculture sectors – specific issues arising in the use of marine GRs in aquaculture and fisheries, and their applications in use of marine life in the food, cosmetic, and agricultural industries, such as aquaculture;

human: human genetic resources and genomic data – specific issues arising in relation to human GRs and human genomic sequence data[2];

bioinformatics – cross-cutting bioinformatics issues that arise in various GR sectors including in sequence analysis (e.g., DNA sequencing, sequence assembly, genome annotation, computational evolutionary biology, comparative genomics, disease genetics, etc.), gene and protein expression (e.g., analysis of gene expression, protein expression, gene regulatory networks, etc.), analysis of cellular organization (e.g., image and microscopy analysis, nuclear organization of chromatin, protein localization, etc.), systems biology issues, and structural bioinformatics.

Caution: Common legal, policy, strategic or operational risks, threats or challenges in GR characterization, research and innovation. The criteria for their inclusion is their practical relevance for the success or failure of GR characterization, innovation or research projects.

Additional resources, tools and references: Other related practical instruments, decision-making tools and standards, for both legal and scientific/technological aspects of this Guides' subject matter.

[2] While human material and data are not covered by the Guide, numerous applications of non-human GRs and GR data involve such subject matter

Get legal advice: the most important message of this Guide is to obtain legal advice on managing the rights and obligations attaching to any GRs, GR data and IP portfolio, starting *before* characterization, innovation and research work, until *after* the end. The second most important message is that this Guide does not provide such individualized advice. These icons point to some key legal issues which require customized legal considerations and some sources to obtain such advice.

Further reading: the law and science of GRs and genomics is evolving and expanding at an unprecedented rate. More information and suggestions for further reading are available on the WIPO TK Division website[3] and in the Guide text marked by this icon.

WIPO products and services: WIPO's Program 4 is continuously developing new products and services on GRs and GR data, as the field evolves. These icons indicate references to WIPO products and services and other programs. Contact the WIPO TK Division at grtkf@wipo.int for further training, capacity building and technical assistance on IP aspects of GRs and GR data.

Example/case study: examples are taken *inter alia* from the WIPO Distance Learning Course on Intellectual Property and Genetic Resources in the Life Sciences (DL-427) and the WIPO-PRV "International Training Program on IP and GRs - in Support of Innovation" and other sources.

D. Scope and structure of the Guide

The Guide is structured in three main parts, which correspond to three phases in the characterization and utilization process:

1. Before characterization
2. During characterization
3. After characterization

The Guide is based on certain standard phases of processing of material and data in the characterization processes, such as material selection (based on considerations including their legal status in terms of ABS frameworks as well as IP legal status), basic sequencing, variant identification, gene mapping, useful allele identification, molecular marker development, linking of genotype and phenotype, downstream data aggregation, etc. While this is an oversimplification of the complex interactions that occur within modern uses in life sciences research between genetic material and data, using this simplification may provide a streamlined reference framework to find certain information.

Within each part (Before/During/After characterization), the IP information is structured into the different branches of IP law, as these are complementary parts of an integrated IP management approach.

1. Scope

The scope of the Guide is focused on the *genomic* characterization of GRs. The genomic, transcriptomic, proteomic and other '-omic' forms of characterization (now leading to entire

[3] https://www.wipo.int/tk/en/ip_rights_management.html

metabolomic datasets mapping metabolisms of entire cells or cell groups), are all closely related and interacting such that their use for GR-based innovation can often not be separated. The Guide focuses the characterization of GRs based on their *genomes*, rather than other biological attributes. On the terminology used to maintain this delimitation of scope, see chapter III.D.2 below.

The Guide addresses the questions of an IP rights management strategy from a legal point of view and not from a business strategy perspective. Considerations on whether to file patent applications, maintain trade secrets or use technological protection measures rely on business strategy, commercial considerations, funding considerations, business models and institutional policies. For business model development for your GR characterization initiative, please see the references provided for further reading.

The scope excludes characterization and genomic sequencing of human genetic resources. It is recognized that there is no absolute boundary between human and non-human GRs, in particular of the human microbiome, and that characterization results of non-human GRs can often lead to breakthroughs in innovation for the use of human GRs, but for reasons of brevity, manageable substantive scope and complexity, diverging applicable legal non-IP frameworks and additional human GR-related IP-specific questions, which would lead beyond the scope of this short Guide, the characterization of human GRs is beyond the scope of this Guide. This exclusion applies only to the *characterization* of human genetic resources, not to innovations resulting from the characterization of non-human GRs which are relevant to inventions for the use of human GRs.

2. Terminology

This Guide uses standard terminology from WIPO for IP terms, including the WIPO Standard ST.26. It uses definitions and terminology defined by the Convention on Biological Diversity for GR terms. There are discrepancies between the uses of terms in IP and in ABS laws, and between the use of terms among different IP laws in different jurisdictions. For details of the use of terminology, please see the WIPO TK Division Glossary on intellectual property and genetic resources.[4]

E. Disclaimers

WIPO neither endorses nor opposes any particular policy or approach to IP rights in GRs management.[5]

This Guide does not provide:

- legal advice on IP rights for specific uses of GRs or specific GR-based innovations and creativity. References to information sources, where such advice or related information are available, are included in the relevant chapters and text boxes;
- an introduction to genetics, GRs management or characterization techniques;
- current information on the status of national or regional legislation applicable to GRs and GR-based innovation. Information on such legislation is available from the WIPO Lex database,[6] and additional references to information sources are in the relevant chapters and text boxes;

[4] https://www.wipo.int/tk/en/resources/glossary.html
[5] This applies to the Guide and all related materials, cases, examples, case studies, practical tips, cautions, further references and other resources referred to in the Guide.
[6] https://wipolex.wipo.int/en/main/legislation

- tools for enforcement of the IP rights acquired over GR characterization and research results. The Guide focuses mostly on acquisition of rights and overall rights management strategy, not enforcement of rights;
- a description beyond a factual description of existing practices in IP rights management. It therefore does not contain any, direct or implied, suggestions or implications for changes to existing policies or practices;
- 'best practices' in any prescriptive, proposed or suggestive sense. The Guide is a purely descriptive account of existing practices as documented in the WIPO's International Training Program on IP and GRs in Support of Innovation, DL-427 Course on IP and GRs in the Life Sciences and other training and capacity building work and inputs from numerous experts;
- a complete or exhaustive account of new technologies for the use of GRs. The Guide provides merely illustrative examples and high-level summaries of technological trends that are transforming the use of GRs;
- an exhaustive description of all the legal frameworks applicable to GRs. The 'further reading' and 'additional resources' elements provide references to information sources. These are often provided by the secretariats or competent authorities responsible for those legal frameworks and should be obtained from those sources;
- the starting point of the Guide is not the application of a particular technological process, such as sequencing, genotyping, ICT platforms or database systems, but the application of IP to the specific subject matter of GR data and material. The Guide does not provide an overview of all the evolving -omics data disciplines surrounding GRs, but rather focuses on genetic sequence data (GSD). See the definitions and 'additional resources'.

Nothing in this Guide should be interpreted as affecting the sovereign rights of States over their natural resources and the authority of national governments to determine access to genetic resources, subject to national legislation.

IV. BEFORE GENETIC RESOURCES CHARACTERIZATION

A. Overview of IP rights relevant to GRs and GR data

This Section provides an overview and introduction to the main branches of IP law relevant for the protection of GRs as well as GR information and data – i.e., which type of GR subject matter is covered, which rights are granted, how to acquire them and how to exercise and enforce them.

Scanning GR characterization and innovation activities *before* conducting the characterization work (with a view to the full range of IP tools available for the protection of GRs and related data) is a critical step for developing a holistic IP policy and rights management strategy for genetic material and GR information and data.

1. Patents

A patent generally grants the patent owner the exclusive right to control who makes, uses, sells, offers for sale and/or imports any invention protected by the patent's claims. Patent claims are sets of sentences, typically appearing at the end of the patent, that describe the invention being protected. In order to obtain a patent, the patent's claims must typically describe an invention that is new, useful and non-obvious in view of the "prior art" (a technical term that generally refers to all the public knowledge and inventions that existed before the filing date of a patent application).

a) What is a patent?

A patent is an award of a limited monopoly from a government for an invention. In the past, governments awarded patents for almost any good or service, whether or not an invention was involved. For example, a king might bestow a patent on a natural resource, like salt, to a trusted ally. In modern times, governments have reduced the scope of patents to protect inventions only. GRs cannot become the subject of a patent *as a natural resource*, but only if they constitute an invention. At present, most patent terms are set at 20 years from the date of the application's filing.

The patent must also satisfy other legal requirements such as time limits related to how long the invention was disclosed to the public prior to the filing of the patent application. Generally, patents will be denied if the invention has been made public prior to the filing of the application, excluding any grace period that may apply. Patents are granted following a formal and substantive examination in which the patent application is thoroughly reviewed by a patent-granting authority. Among other things, the patent examiner will compare the prior art relating to a pending application against the application's claims in order to determine if the claimed invention provides a novel and non-obvious advance over the prior art.

Caution:

A patent application must be filed ***before*** publicly disclosing any important results of your GR characterization, innovation and research activities that may lead to a valuable product or technology. If you intend to keep open the possibility of filing patent applications, this caution applies also for pubic research institutions and academic research institutions. You should therefore *not* disclose your characterization or research results prior to having considered if you might file a patent application in the future to which those results might constitute material prior art and, if so, you should file the patent application *before* publishing the research results. For specific details see chapter V.B and VI.B.

Practical Tip

If your characterization project or your research institution requires the publication of research or academic works, the necessity for you to regularly issue such publications can be accommodated by implementing a publication clearance procedure within your institution, which reviews draft journal and conference submissions for patentable inventions prior to their publication. Necessary measures to safeguard your options for filing potential future patent applications can then be taken at the right time, depending on the IP policy and strategy of your institution and your GR characterization and research project. Before publishing data which could constitute prior art that might be material to potential future patent applications, which you might file, you should seek legal advice.

Based on the principle of territoriality of patents, a patent title is valid always only in the limited jurisdiction for which the patent-granting authority that has issued it is competent. It is also only valid if it has not had a successful challenge against it in a court or before the relevant patent-granting authority.

Patent laws normally recognize patent protection for different types of GR-related inventions. At the same time, most patent systems provide uniform treatment for all inventions, regardless of the type

of invention and the field of technology, i.e., they implement a principle of non-discrimination as to field of technology for the availability of patents. The term “patents” usually refers to “patents of invention”, which are also referred to as “utility patents”, and which protect chemical compositions, machines, processes and the other kinds of inventions that are valuable because of their industrial applicability.

Plant patents

Some jurisdictions also grant “plant patents”, which are relevant to GR-based inventions. For example, in the United States, plant patents may be obtained on “any distinct and new variety of plant, including cultivated sorts, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state.”

Additional resources

If you intend to protect outcomes of your GR characterization or research project in jurisdictions which make available plant patents and you believe your characterization and research results might be eligible for plant patent protection, please consult specialized legal advice.

Petty patents and utility models

A similar situation applies to another category of patent titles which are available in some jurisdictions, namely “petty patents”, also referred to as “utility models” or “utility innovations.” Normally, the requirements for the registration of utility models are less stringent than those for the grant of a patent of invention. Consequently, also the scope of the rights granted, and the term of the rights are normally narrower and shorter respectively, compared to those of patents of invention. In practice, petty patent or utility model registrations are typically filed for innovations of an incremental nature that might not satisfy the criteria for patents of invention, particularly through a lack of inventive step. In certain jurisdictions, utility model protection can only be obtained for certain fields of technology and only for products but not for processes.

Additional resources

If you intend to protect outcomes of your GR characterization or research project in jurisdictions which provide petty patents or utility models and you believe your characterization and research results might be eligible for such protection, please consult specialized legal advice.

b) What kind of genetic resources, information and data can be the subject of a patent?

The question about which type of GR subject matter – GRs, related information and data – can be the subject of a patent, can be answered by classifying the subject matter from an IP perspective. It is worthwhile differentiating the subject matter frequently referred to as GSD into different categories of IP subject matter.

1. Nucleotide and/or amino acid sequences

1.1 a "nucleotide and/or amino acid sequence" as described by a sequence listing which, in the meaning of patent law, constitutes a discovery. Such sequences disclosed in sequence listings do not provide a solution to a specific problem in the relevant field of technology and therefore do not constitute an invention. In accordance with the product of nature doctrine, such subject matter is not patentable.

1.2 a "nucleotide and/or amino acid sequence" as described by a sequence listing which, in the meaning of patent law, constitutes an invention. The sequences disclosed in the sequence listings provide a practical solution to a specific problem in their field of technology and therefore constitute an invention. However, the practical solution provided is not new, non-obvious and industrially applicable. Therefore, such subject matter is not patentable.

1.3 a "nucleotide and/or amino acid sequence" as described by a sequence listing which, in the meaning of patent law, constitutes a patentable invention. If, according to the applicable patent law, the sequence falls within the scope of patentable subject matter and the sequence is new, non-obvious and industrially applicable, such an invention becomes patentable, provided that the invention is sufficiently disclosed in the patent application, including through the sequence listing, for a person with average skill in the art to practice the invention.

2. digital "sequence listings"

2.1 a “sequence listing” which discloses a nucleotide or amino acid sequence and other available information, but which does not itself constitute that nucleotide or amino acid sequence. It is not the sequence but rather a description of the sequence and it is therefore not patentable. Nevertheless, its disclosure to the public makes the sequence itself unpatentable, because the sequence then becomes part of the prior art.

2.2 a sequence listing which is part of a patent application claiming a nucleotide or amino acid sequence under 1.3 above. If, according to the applicable patent law, the sequence falls within the scope of patentable subject matter and that sequence is new, non-obvious and industrially applicable and if the patent application, including the sequence listing, sufficiently discloses the claimed sequence for a person skilled in the art to practice the invention, it may make that nucleotide or amino acid sequence patentable. Only in that sense is the sequence described by the sequence listing patentable.

The patent system functions as an information system for the disclosure of inventions which are new, non-obvious and industrially applicable, and fall within a certain defined scope of patentable subject matter, as is the case for many GR-based inventions. The patent system can thus provide useful information on relevant new technological developments, including, among other things, the concrete applications of specific sequences. Such information is often compiled in form of prior art searches, freedom-to-operate analyses or patent landscape reports.

Before starting a GR characterization project, it is advisable to think through the intangible assets and subject matter of the project and relate them to these layers of subject matter.

2. Copyright

a) What is copyright?

Copyright and related rights law deals with the rights of authors and intellectual creators in their creations. It is also referred to as author’s rights and neighboring rights law, respectively, and has the objective to stimulate human creativity and to make the results of that creativity available by disseminating it widely. Copyright and related rights law deals with particular forms of creativity,

including, under certain conditions, those concerned with the annotation of existing scientific works, information and data, such as GR data. It affects virtually all forms and methods of scientific and public communication, including both printed and digital scientific publications, software and computerized systems for the storage and retrieval of digital information, such as sequence data in digital form.

Copyright and related rights law protects only the *form of expression* of ideas, and not the ideas themselves. The creativity protected by copyright law is creativity in the expression as well as the choice and arrangement of words, information, and its presentation and composition. Copyright law protects the owner of economic and moral rights in artistic works against those who "copy"—those who take and use the *form* in which the original work was expressed by the author.

The copyright for scientific works expressing your intellectual creativity will generally, at least in the first instance, belong to the author. However, certain national laws also provide that, where a work is created by an author employed for the purpose of creating that work, the employer, not the author, is the owner of the copyright in that work. The author may transfer the economic rights to individuals or companies best able to market the works, in return for royalties.

The transfer of copyright may take one of two forms: assignment or licensing. An assignment is a transfer of a property right. Under an assignment, the right owner transfers the right to authorize or prohibit certain acts covered by one, several or all rights under copyright. The person to whom the rights are assigned becomes the new copyright owner. Copyright rights are divisible, so it is possible to have multiple right owners for the same or different rights in the same work.

b) What kind of genetic resources information and data can be the subject of copyright protection?

The subject matter of copyright protection includes every production in the scientific, literary and artistic domain, whatever the mode or form of its expression. For a work to enjoy copyright protection, however, it must be an *original* creation. Raw sequence reads, early-stage alignment files, and often even annotation files of genomic sequence data (see section V below) are *not* an original creation. The ideas and scientific content in the work do not need to be new (in contrast to the subject matter of patent protection), but the *form*, whether it is scientific, literary or artistic, in which the ideas and content are expressed must be an *original* creation of the author. And, finally, copyright protection is independent of the scientific truth, experimental verifiability, methodological validity or technological applicability of the scientific content your work. A scientific work will be protected whether it be considered, according to scientific method, true or untrue, verifiable or unverifiable, technologically or industrially applicable or inapplicable – because the use to which a scientific work may be put has nothing to do with its copyright protection.

To be protected by copyright law, an author's works must be *original*. This means that the works must originate from the author; they must have their origin in the labour of the author. But it is not necessary, to qualify for copyright protection, that works should pass a test of imaginativeness or inventiveness. The work is protected irrespective of the quality thereof and when it has little in common with literature, art or science. Copyrighted works may include purely technical guides or engineering drawings, or even maps, including genome maps. This demonstrates that it is not mere ideas, as such, that are protected by copyright, but the *form* of expression. Exceptions to the general rule are made in national copyright laws by specific enumeration; thus laws, official decisions or mere news of the day are commonly excluded from copyright protection.

Practically all national copyright laws provide for the protection of the following categories of works:

(1) literary works: novels, short stories, poems, dramatic works and any other writings, irrespective of their content (non-fiction or fiction), length, purpose (science, information, amusement, education, advertisement, etc.), form (handwritten, typed, printed; book, pamphlet, single sheets, newspaper, magazine); whether published or unpublished;

(2) maps and technical drawings: these may include genome maps resulting from WGS;

(3) artistic works: whether two-dimensional (drawings, paintings, etchings, lithographs, etc.) or three-dimensional (sculptures, architectural works);

(4) photographic works: irrespective of the subject matter (e.g., plants, animals, microbes, cellular, sub-cellular or molecular subject matter, etc.) and the purpose for which made (e.g., scientific discovery, art, etc);

(5) computer programs (either as a literary work or independently);

(6) musical and cinematographic works (not relevant to GRs or this Guide).

For this range of subject matter, owners of copyright in a protected work may use the work as she or he wishes and may exclude others from using it without his or her authorization.

What is meant by “using” a protected work? Most copyright laws define economic rights as the acts or “uses” that cannot be performed or made by persons other than the copyright owner without the authorization of the copyright owner. Such acts usually include at least the following:

- *reproduction* of the work in various forms;
- *distribution* of copies of the work;
- *translation* of the work into other languages;
- *adaptation* of the work:
- *public performance* of the work; and
- *broadcasting* or other *communication of the work to the public*.

Besides these economic rights to use the work, copyright owners also have the moral right to be recognized as the authors of their works (the ‘right of paternity’).

c) Why is copyright important for genetic resources information and data?

In principle, copyright might apply to all kinds of original scientific texts, drawings, graphics, diagrams, photographs, annotated data compilations and computer software. For such protected works, copyright would grant the following economic rights:

- the *right of reproduction*: the right to prevent others from making copies of your works without your permission is the most basic right protected by copyright legislation. The right to control the act of reproduction – e.g., the reproduction of scientific journal articles, book chapters or books by a publisher – is the legal basis for many forms of economic exploitation of your protected works. This right of reproduction also exists in the digital environment, as set out in the WIPO Copyright Treaty (WCT);
- *distribution rights*: other rights are recognized in national laws in order to ensure that this basic right of reproduction is respected. Many laws include a right to authorize the distribution of copies of works. The right of reproduction would be of little economic value if copyright owners could not control distribution of copies of their works made with their consent. The right of distribution usually terminates upon first sale or transfer of ownership of a particular physical copy. This means, for example, that when you sell or otherwise transfer ownership of a copy of your scientific journal article or book, in which you publish the GR characterization

data resulting from your work, the subsequent owner of that scientific journal article or book may give that article or book away or even resell it without your further permission, including the characterization data in the form you have described them in that text.

Another right that is gaining recognition and is included in the WCT for the digital environment, is the right to authorize rental of copies of certain categories of works, such as computer programs and audio-visual works. This became necessary in order to prevent abuse of the copyright owner's right of reproduction when technological advances made it easy for rental shop customers to copy such works.

Finally, some copyright laws include a right to control importation of copies as a means to prevent erosion of the principle of territoriality of copyright. The right is based on the premise that the legitimate economic interests of copyright owners would be endangered were they not able to exercise their rights of reproduction and distribution on a territorial basis.

- *Rights of communication to the public, broadcasting and making available*: another major category of rights includes the right of communicating works to the public by means of wires or cable, including broadcasting works, and of making works available to the public. When a work is communicated to the public, a signal is distributed by wire or wireless means for reception only by persons who possess the equipment necessary to decode the signal. For example, cable transmission is a form of communication to the public. Under the Berne Convention, authors have the exclusive right to authorize the communication of their works to the public. Since the global digital environment has introduced interactive communications that enable users to select works to be delivered to their computers or other devices, the right of communication to the public has been widely discussed and different opinions have been expressed as to which right should be applied to these activities in the online environment. The WCT clarifies that it should be covered by an exclusive right, which the Treaty describes as the authors' right to authorize the making available of their works to the public "in such a way that members of the public can access these works from a place and at a time individually chosen by them" (Article 8). Most national laws implement this right as a part of the right of communication to the public, although some do so as part of the right of distribution.
- *Right of translation and adaptation*: the copyright right owner also holds the right to authorize the acts of translating or adapting the protected work. "Translation" is defined as the expression of a work in a language other than that of the original version. "Adaptation" means the modification of a work to create another work, for example adapting a novel to make a film, or the modification of a work for different conditions of exploitation, e.g., by adapting a textbook originally written for a scientific audience to make it suitable for a non-scientific audience. Adaptations and translations are themselves works protected by copyright. When an adaptation or translation of a work is published, both the owner of the copyright in the original work and the owner of copyright in the translation or adaptation have to give their permission. The increasing ease of transforming works in digital format has raised discussions about the scope of the right of adaptation in the digital environment. With digital technologies, users can easily manipulate text, data compilations, images and sounds to create user generated content. The same would apply for your digital sequence information resulting from you GR characterization work.
- *Right of public performance* (this right is not relevant for this Guide).

The final category of rights granted by copyright are the moral rights of the author. Article 6*bis* of the Berne Convention provides that its contracting parties shall grant authors the following moral rights:

i. the right to claim authorship of a work (the right of paternity or right of attribution);

ii. the right to object to any distortion or modification of a work, or other derogatory action in relation to a work, which would be prejudicial to the author's honour or reputation (the right of integrity).

Moral rights are only granted to individual authors and the Berne Convention requires these rights to be independent of the economic rights. In many national laws your moral rights as author will remain with you even if and after you have transferred your economic rights to your copyright works.

Licensing means that the copyright owner retains ownership but authorizes a third party to carry out certain acts covered by copyright, generally for a specific period of time and for a specific purpose. For example, the author of a scientific book may grant a publisher a license to make and distribute copies of that book.

Licenses may be exclusive, with the right owner agreeing not to authorize any other party to carry out the licensed acts; or non-exclusive, which means the right owner may authorize others to carry out the same licensed acts.

Licensing may also take the form of collective administration of rights. Under collective administration, authors and other right owners grant exclusive licenses to a single entity that acts on their behalf to grant permission for third-party use, collect and distribute remuneration, prevent and detect infringement of rights, and seek remedies for infringement. Collective administration offers advantages to authors, in particular by providing a single, central source to ensure that mass use of a work takes place only with the necessary permission. This is increasingly important as digital technologies allow multiple possibilities for the unauthorized use of copyrighted works, but at the same time can facilitate the rapid, automated granting of licenses and the inclusion of licensing information in metadata.

Various cooperation projects have been set up according to a model whereby contributors give up certain rights described in the licensing terms adopted for the project, such as the Creative Commons licenses and the General Public License for free software. Right owners thereby leave their contributions free for others to use and adapt, but with conditions such as requiring that subsequent users must also do so.

3. Protection of trade secrets and other undisclosed information

Trade secrets and the protection of undisclosed information play an important practical role in the transfer and utilization of many GRs and GR data, even though these forms of protection often receive little attention.

a) What is a trade secret and the protection of undisclosed information?

In general, the term 'trade secret' refers to a body of commercially valuable information which is kept secret in order to prevent competitors from learning about and using it and thus creating an advantage in competition. Secret information may be defined as information that is not generally known among, or readily accessible to, others who normally deal with the kind of information in question.

Described in simplified terms, a trade secret is a type of IP right which comprises two elements: The first element is "trade", which means that the undisclosed information must have a *commercial* value. This could, for example, be a practice, process, design, instrument, pattern, formula or any commercial method as well as a compilation of information, such as, e.g., some forms of GR information or sequence data , which may constitute an economic advantage over competitors. A

trade secret may also relate to technical matters, such as a composition or design of a product, a method of manufacture or know-how necessary to perform a particular operation. In principle, any confidential business or commercial information which provides an undertaking with a competitive advantage may qualify as a trade secret.

The second element is “secret” which means that the information is not generally known or reasonably ascertainable by others who normally deal with the kind of information in question. The owner of the information needs to prevent others from improperly acquiring, disclosing or using the information in order to be protected. As such, the protection of a trade secret lasts only for as long as the information fulfils the requirements of protection.

In order to determine, whether and, if so, how you can and want to apply the protection of undisclosed information and trade secrets in your GR characterization, research or innovation project, you need to analyse which type of information in your project can be protected through this tool.

b) What kind of GRs, information and data can be the subject of a trade secret or the protection of undisclosed information?

Based on these two basic elements, the conditions for legal protection which are common to the definitions in most jurisdictions, are that:

i. the information is not generally known to the public,
ii. the information comprises an economic benefit to the owner just because it is not generally known to the public, and
iii. the owner makes all necessary efforts to keep the information secret.

At international law, these three factors define the protection of undisclosed information under Article 39 of the TRIPS Agreement, which provides that “natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices, so long as such information: (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.”

This provision however sets merely a minimum standard for the protection. Applied to GRs, this provides an important level of legal certainty for the use and transfer of undisclosed GRs and GR data, such as *inter alia* sequence data.

In all jurisdictions, trade secrets are protected because of the three conditions and are not registered IP rights, such as patents. In contrast to other IP rights which are acquired through formalities, such as registration or applications, with subsequent publication, trade secrets are not disclosed, i.e. their protection is not based on their registration but on their secrecy.

The owner of trade secrets needs to protect the information by applying special protection measures to the information, such as legal security measures, e.g. non-disclosure agreements (NDAs), non-compete obligations and penalty clauses. Additionally, non-legal measures include restricting access to trade secrets to those persons who need to know, marking documents as confidential, using separate locked depositories, authorization and access controls, computer security measures, internal policies, shredding, or technological protection measures.

The absence of formalities associated with registered IP rights also implies that a third party, which is not bound by a signed agreement, is not prevented from independently duplicating and using the trade secret information once it is discovered. Especially in the life sciences sectors this situation can occur in the case of reverse engineering, for example of chemical compounds of pharmaceutical drugs or crop protection products, such as pesticides.

Usually, trade secrets do not have a limited term of protection, since the protection lasts as long as the requirements of protection are fulfilled. In general, trade secrets are protected without registration or other procedural formalities (e.g. application, examination, registration, etc.). Thus, trade secrets have sometimes been called a 'do-it-yourself' form of IP protection.

c) Comparison to patents

Trade secrets	Patents
No registration – immediately available – no registration fees, but cost to keep information secret	Registration – registration fee – time for registration procedure
no time limitation	limited in time (20 years/SPC)
no public disclosure	public disclosure
large protection due to large subject matter	limited subject matter
more difficult to enforce	easier to enforce erga omnes

Since the protection of trade secrets is merely based on the secrecy of the protected information and not limited to a certain term, the protection of trade secrets may be extended indefinitely. In the case of some uses of GRs, this may constitute an advantage compared to other IPRs such as patents, which last only for a specific term.

Trade secrets are often used in complementarity to patent protection, because of the advantages and limitations inherent in the criteria for protection and scope of rights in the protection of trade secrets.

One significant advantage of trade secrets in the context of the utilization of sequence data, which is increasingly characterized by a rapid turn-over of innovations, is the immediacy of availability of protection. In contrast to patents, there is no extensive application and examination process, which appear time-consuming for some high-speed innovation cycles based on GR data and their utilization.

Other advantages of trade secrets compared to registered IPRs are that trade secrets can be protected for an unlimited period of time and that there are no protection fees based on a registration procedure at a competent authority and for procedural formalities. This does not imply, however, that there are no costs to ensuring trade secret protection, since the costs of implementing reasonable steps for the maintenance of the secrecy of the information can be significant, depending on the circumstances. The disadvantage of trade secrets is that there is (almost) no protection if the information is no longer confidential. In addition, there is no formal procedure in case of an infringement of trade secrets, such as the formal procedures in the case of a patent infringement.

In terms of the practical use of GRs, most licenses of GR-based technologies are hybrids which cover both patents and trade secrets. Using patents and trade secret protection together in an effective and strategic manner leads to strong partnerships and strong legal certainty over the results of the utilization of GRs. Thus, within many successful GR-based innovation programmes, the protection of genetic material and data as trade secrets, which form unpatentable outputs of the

programme, are complementary to the patent protection of those outputs of the same programme which are patentable inventions – both forms of protection form corresponding parts of a comprehensive IP strategy for the overall innovation program.

For example, in many breeding programs, elite parental breeding lines of plant genetic material or animal semen and eggs are transferred and maintained as trade secrets. In the use of microbial GRs for production of industrial enzymes, microbial strains and their characterization data are often maintained as undisclosed information in combination with contractual arrangements for the exchange of material and data.

4. Technological protection measures

After reviewing the legal framework of IP rights and other rights protecting innovation such as the protection of undisclosed information and unfair competition law, it is worth addressing briefly supplementary technological protection measures to protect the innovation. Since content and innovation can be easily reproduced, innovators need to safeguard their protected innovation including in the digital environment. This is especially important due to the dematerialization and digital transformation of the use of GRs, where digitized GR data can be disseminated digitally in a very easy way.

Right holders may employ technological protection measures (TPMs) to prevent unauthorized access to, or use of, an innovation, scientific work or body of information. TPMs cover many different types of technologies which are used to control access to protected content. Especially copyright has long been enforced through TPMs, specifically in the context of so-called digital rights management (DRM).

Content that could be protected by TPMs may include copyright protected content, such as digital music, movies, games, software, but also GR-related information, such as GR data and scientific literature about GRs. DRM and generally the technological enforcement of law, based on digitization and the online availability of information, can be used to enforce existing legal and contractual rules in a new and efficient manner.

B. Assessing legal encumbrances for your GR characterization and innovation initiative

The products and processes which you use for, and will produce from, your GR characterization and innovation projects are inherently technologically complex. Even a quick review of the “materials and methods” chapters of the scientific journal articles, that you will have been using to develop your GR work, will show a multitude of parts and processes which are used in the development and commercialization of a GR-based product or process. This technological complexity gives rise to an equivalent and parallel legal complexity that surrounds the various technical components and processes of your GR characterization work.

1. Patents

Because of this surrounding landscape of legal encumbrances on your use of the genetic material, data, products and processes that you utilize in your GR characterization and innovation work, there is a normal risk of infringement liability, which you have to manage during your GR-based work. The tool to manage this risk is called a freedom-to-operate (FtO) analysis. An FtO analysis is a specific assessment of your FtO for a specific technology, at a specific time, in one or more specific

jurisdictions. For a specific FtO analysis of your GR-characterization or innovation work, you should seek specialized legal and technical advice. A generalized description of FtO analyses, such as provided in the present Guide, can never replace the customized and specific FtO for your GR-based research and innovation work.

Your FtO you can generally think of as your ability to proceed with your research, development, commercialization, marketing and/or use of a new product or process resulting from your GR-characterization and innovation work with minimal risk of infringing the unlicensed IP or ABS rights of third parties.

At this stage of your work, you do not yet need a full-fledged legal opinion on your FtO as will be preferable when you decide, after characterization, about putting selected outcomes of your characterization work into development, production and potential commercialization of new products and processes. Therefore, at this stage of the process, your initial FtO analysis may just consist of a patent landscape surrounding your GR-based innovation work. Multiple institutions, including WIPO, produce patent landscapes and for the production of patent landscapes see the tools offered by the Technology and Innovation Support Division in the IP for Innovators Department of WIPO.

WIPO resources: For a general introduction to FtO and FtO analysis, see the WIPO Magazine report on the subject. For patent landscapes on GRs see the patent landscapes produced upon request by the Technology and Innovation Support Division in the IP for Innovators Department of WIPO.

2. Copyright

If you are planning to work with extensive preexisting GR data sets and scientific literature, you may need to use other parties' copyright material as part of your GR characterization and innovation work. When using other people's copyright material, it is important to ensure that you abide by copyright law and any relevant licenses and agreements. This section provides you with the starting point for your rights management process to manage copyright in your GR characterization and research process (Figure *4.2*).

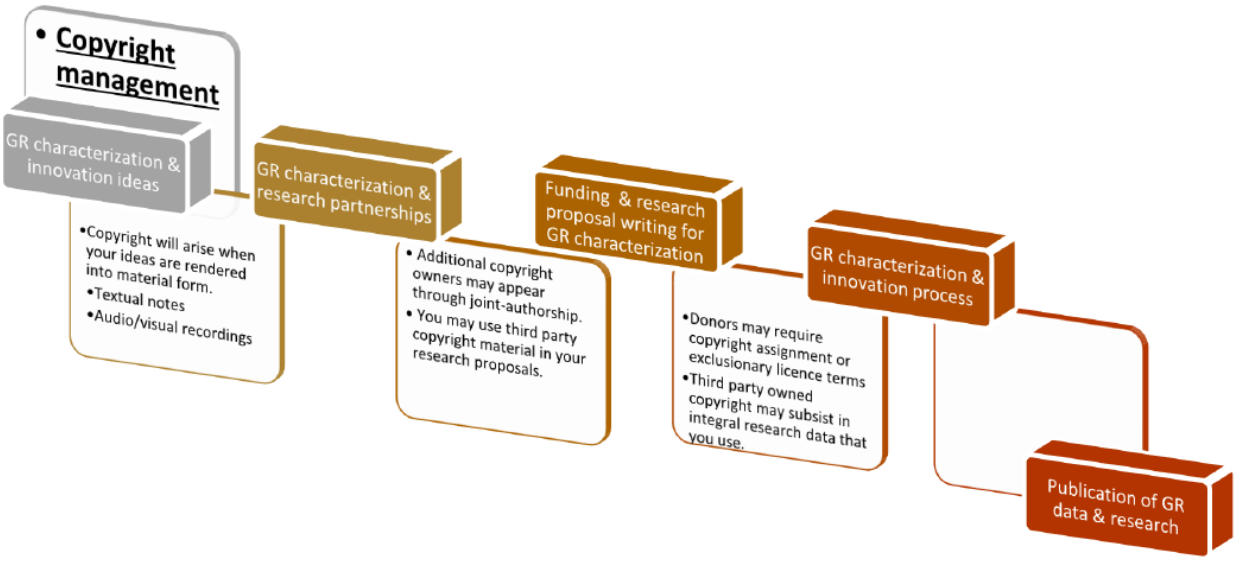


Figure 4.2: some illustrative items of a copyright management process

As a starting point, please check your institutions policies and by-laws for the obligations of employees, non-employees and partners with regard to ownership and management of copyright. As explained above, copyright in the scientific works that you create may be owned by you, or jointly with other creators, depending on the circumstances of its creation. It could also be owned by your institution or another legal person or entity, depending on the applicable policies and by-laws.

You may also be required via funding or other contractual agreements to transfer copyright in your research work to another party. This may have an effect on the copyright management of your GR characterization results, for example, in that it may limit your abilities to publish such work separately.

Practical Tip

Obtain and study relevant information from your institution to determine arrangements of copyright ownership applicable to your GR characterization and innovation work, including:

- IP, particularly copyright, provisions in the relevant policies, statutes and by-laws of your institution;
- Relevant funding agreements that might be applicable to your GR characterization and innovation project in so far as they contain IP, ABS or other intangible asset ownership and management clauses;
- Your employment contract(s) with the institution, in so far as they contain IP, confidentiality or other intangible asset ownership or management clauses;
- Information and advice from the relevant office and department of your institution that can provide you with additional specific guidance or information.

Besides the copyright ownership and management arrangements at your institution, you will also need to obtain and study those between your institution and third parties when you undertake some of the standard steps in initiating your GR characterization and innovation initiative, such as:

- defining your GR research, characterization and innovation objectives
- identifying potential funding sources (whether private or public sectors)
- investigating potential for publication or commercialization of your work.

As you undertake these steps before your GR characterization, you may need to negotiate contracts, confidentiality agreements, IP transfer agreements and non-disclosure agreements (NDAs, see previous sub-chapter).

One effect of such agreements is that, if you include third parties' copyright protected material in your work, you may be required to provide this to other parties. It is therefore important to secure authorization of relevant right holders to use their copyright materials (whether it is GR data sets, data compilations, scientific literature, etc.) if it is required to comply with contractual obligations or your GR characterization and innovation goals cannot be achieved without the copyright material.

Since GR- and GR data-related copyright materials are often central to GR characterizationtt initiatives, it is therefore critical to obtain the necessary copyright clearances before you begin your characterization, research and innovation work.

Caution
To avoid potential future complications with copyright infringement in your GR characterization or innovation work, you should ensure that you contact copyright owners of the main scientific works and information inputs that will be critical to your GR characterization or innovation initiative before you begin investing in the use of their works. Before you begin your characterization or innovation initiative, you should be sure that you can secure all the necessary rights and authorizations to use the mission-critical copyright materials of your GR characterization or innovation initiative.

Besides ensuring that you can obtain copyright clearance for the critical scientific works and information of others, which you need to use for your GR work, you may also wish to consider whether you can and want to retain certain personal rights or rights for your institution related to copyright.

Practical Tip

Before you begin your GR characterization or innovation initiative, consider if there are any – and if so which – rights for your institution, which it wishes to retain, or personal rights, which you may want to retain, once you are undertaking your GR characterization and innovation work (for example, the right to publish).

V. DURING GENETIC RESOURCES CHARACTERIZATION

During the GR characterization and innovation process, there are at least two simultaneous, closely interrelated processes that you will need to manage in parallel. The first is the GR characterization, research and innovation process, which follows your scientific strategy. The second is the rights acquisition and management process, which follows your legal strategy. Both should ideally be aligned, mutually reinforcing and simultaneously developed and implemented. This Part of the Guide will give you an overview of GR management process through a simplified description of a typical standard plant genomic resequencing process. Practical case studies, such as for sugar palm, can be found on the WIPO TK Division service tile for IP rights management in GRs and GR data.

A. GR management process

GRs consist of the inherited genetic material that perpetuates an organism. Thus, GRs can be used both to reproduce and, through hybridization and selection, to change or enhance the organism. More recently such changes and enhancements can also be made directly through genome editing techniques and new breeding techniques (NBTs). Such changes to GRs often lead to the creation of significant IP, including patentable inventions or know-how and information which may be legally protected through trade secrets, etc. However, this section does *not* describe such changes to GRs. It focuses only on the description and characterization of GRs which generates genomic sequence or other characterization data.

In this regard this section, for reasons of brevity, is deliberately focused and limited in two ways: (1) first, it focuses on the *genomic* characterization process: there is extensive, important and highly

valuable characterization work closely related to the processes described here, such as proteomic, metabolomic and other omics characterization. This work is closely related (for a simplified schema see Fig. 5.4) but falls outside the scope of this section. (2) second, often a GR-based research and innovation project will not be oriented only to characterize material, but will pursue more complex research and innovation goals. This section covers only the characterization work and those innovation processes which build upon the generated characterization data.

With these limitations in mind, let us look at a typical GR characterization process.

1. Genomic characterization

Diverse methods that offer different benefits and trade-offs are available for *genomic* characterization of GRs, and their choice will depend on the aim and available resources. The process of determining the genetic composition of a GR is termed *genotyping*, and the most comprehensive and the most expensive method is *whole genome sequencing*, which will read all of the DNA sequences found in the genome of the organism. Currently, whole genome sequencing is typically done using 'next generation sequencing' (NGS) technology, which determines the genetic sequence by simultaneously reading millions of short segments in the genome. These 'short reads' then need to be *assembled* into a complete sequence using computational analyses.

The cost, equipment, and skill sets required to read and analyse a whole genome DNA sequence has been significant so far, but these barriers are getting lower as time progresses and sequencing costs drop. Commercial services that provide whole genome sequencing and bioinformatics analyses also exist in many countries. In addition, for some types of analyses, good inferences regarding the GR can be made just by sampling some of the highly variable DNA sequences found in the genome, thereby reducing the cost and workload required for downstream analysis. The level of sampling can also be lowered further in some usage types to further reduce the cost and complexity of downstream data processing. This process of sampling merely a part of the genome can be done by selective sequencing or DNA marker assessment.

Practical Tip

The cost of Sanger sequencing (which covers 500-700 bases, typically for sequencing a short sequence) is typically calculated based on the number of samples, but the cost of whole genome sequencing using NGS is usually based on the total number of bases, calculated by multiplying genome size by sequencing coverage. Service providers typically will ask about those two parameters to provide a quote for the cost of sequencing. Since a NGS sequencing library is created by breaking down the genome randomly into small fragments, NGS is typically done by sequencing the genome multiple times to ensure that each segment in the genome is represented in the final output. Obviously the higher the coverage, the better, but the cost will also increase accordingly. Depending on the intended application of the sequencing results, the minimum required coverage can vary, as outlined in https://genohub.com/recommended-sequencing-coverage-by-application/. Organisms with larger genome sizes are generally more costly to sequence.

a) Variant identification

Once the DNA is genotyped, the next task is to identify parts of the DNA that vary between GRs. Even the DNA of species as diverse as humans and chimpanzees only differ by less than 2%, yet it

is this small proportion of sequence differences that also cause the differences in the appearance and behaviour of both species. Even more specific are the genetic differences between individual genotypes of the same species. DNA variants in whole genome sequencing data are typically identified by aligning the sequencing reads to a relevant reference genome and identifying DNA sequences that differ from the reference genome sequence.

b) Gene mapping

Another important part of genomic analysis is deciphering the function of the DNA sequences and their effects on traits of interest. Traits are mostly coded by DNA segments, called 'genes', and a plant genome typically contains tens of thousands of such coding sequences, whereas a viral genome might have just a few dozen. When a reference genome was constructed, an annotation file was also generated, which contains information regarding which parts of the chromosomes contain which genes. Some basic information regarding each gene's function, predicted by annotation software, are also included. However, the link between those functions and observable traits is not always obvious. For example, some disease resistance traits are caused by mutations in genes that produce proteins that attach a phosphate group to another protein. Thus, knowing the function of a gene product does not always make it easy to predict its effect on traits.

c) Identification of useful alleles

The DNA in the genome of all organisms are not static, as new variations continuously arise and drive the evolution of the organism. Some of those new variants are detrimental, while others can create beneficial effects on trait expression. Different variants of a gene are known as alleles and whole genome sequence data can be used to mine such alleles and narrow down the GRs that need to be screened in breeding programs. Allelic data can also help in pinpointing the causal gene following genetic mapping studies, which typically locate the mapped trait in an interval that may contain numerous candidate genes. By focusing only on genes with consequential DNA mutation, irrelevant genes can be eliminated to simplify gene identification.

d) Molecular marker development

DNA markers are typically DNA sequences with known location that can be used to assess DNA variations in that particular location.

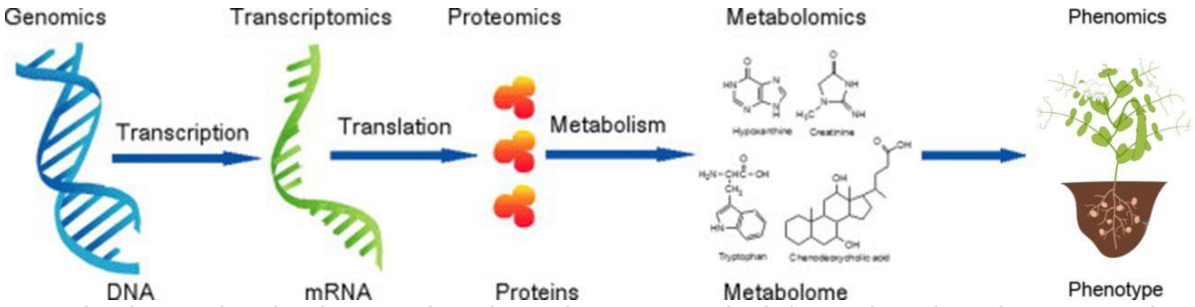
DNA markers are developed for various purposes, such as diversity assessment, genotyping a specific location in the chromosomes, or to aid the detection and selection for a particular trait. DNA markers used for diversity analysis are usually designed to sample chromosome regions with high variability, such as those containing microsatellite DNA. Markers for chromosomal location are typically used for genetic mapping or tracking recombination, while markers for traits are used in breeding programs to aid or replace physical trait observation.

Caution

Some DNA sequence variations, especially those that cause or are linked to useful traits are patentable in some countries. In other countries where DNA sequence patents are not available, methods and markers to detect those variants are patented instead. It is advisable to check if such patents exist before developing and applying DNA markers in commercial settings.

e) Transcriptomic, Proteomic and Metabolomic characterization

Figure 5.4. Gene expression and the omics



DNA is the molecule that carries the primary genetic information, but the expression of this information to produce certain traits occurs in distinct stages and is influenced by the environment where the organism grows. The genes in the DNA are first translated to produce RNA transcripts, which are then translated into proteins. The proteins may be incorporated in the structural components of the organism, involved in biological processes such as growth and metabolism, or perform molecular functions, such as catalysing enzymatic reactions and transport of molecules across cell membranes. Each stage has its own regulatory mechanisms, so in order to understand how a particular trait manifests under certain environmental conditions may require complex experiments and observations of those stages. As technological developments increasingly enable such observations to be conducted in a high-throughput manner at molecular level, this gives rise to the field of transcriptomics (study of RNA transcripts), proteomics (study of proteins), and metabolomics (study of metabolites).

f) Link between genotype and phenotype

The results of genetic mapping, allele mining, transcriptomic, proteomic, and metabolomic studies can establish the links between DNA variation to expressed traits. Once such a link is established, it becomes possible to predict the presence or absence of a trait by relying on DNA sequence data alone. This confers several advantages, as DNA samples are easy to collect from a very small amount of tissue samples at various conditions, and DNA samples are easy to handle, and they tolerate long term storage very well.

B. Rights management process and legal strategy

During the characterization phase, it is important to continue to implement the rights management strategy which you considered, planned and initiated before you began your GR innovation project. Besides the GRs and GR data management processes of your characterization initiative, this is the second process which you need to manage while you characterize and innovate based on the GRs. While it is the main focus of this Guide, this process needs to be highly customized and continuously adjusted during the characterization and innovation process that you are undertaking.

Get legal advice

If IP and ABS legal advice is available within your institution, it is preferable, for this purpose, to consult the relevant department in your institution, such as the Technology Transfer Office, IP legal team and/or ABS focal point. You may wish to identify new

relevant IP or ABS subject matter as you go through your GR characterization and innovation process.

The following subsections provide you with a few illustrative, standardized steps that you can take in relation to the different forms of IP in continuation of the considerations and steps you have already taken before your research, characterization and innovation work.

1. Patents: laboratory notebooks and invention disclosure forms

During the characterization process, the most important steps and measures for you to maintain in relation to patent law and practice are to secure and remain within your freedom-to-operate; to maintain potentially patentable subject matter that you are generating undisclosed until you have filed relevant patent applications, or decided not to do so; and to document any inventions you are generating through your characterization, research and innovation work as an optimal basis for your patent strategy. Two main and standard tools for this are systematically using laboratory notebooks and invention disclosure forms. This section will provide you an introduction and give you some examples on these two tools.

a) Lab notebooks

A laboratory notebook is a daily record of every experiment that you do, a daily record of your thoughts about each experiment and the results thereof, the basis of every paper and thesis you write, the record for every court of law or patent office in case of patent disputes, and a record that will enable successive researchers, working on the same projects to pick up where you left off or reproduce your results without difficulty.

Laboratory notebooks are owned by the researchers or the organization who paid for the research work, depending on applicable policies, by-laws and employment contracts (see section IV above). Lab notebooks come equipped with carbon copy paper in-built (the best and safest approach) or, alternatively, you should make photocopies of the complete notebooks. Lab notebooks are archived in an easy access system since it is important to secure the data record.

Practical Tip

In order to keep track of aspects of our GR characterization and innovation work which might in the future become relevant to your IP strategy and management, you may wish to keep systematic lab notebooks in your lab or office and establish a consistent policy for maintenance of the notebooks. You might also wish to use WIPO's one-stop resources to obtain timestamps and other rights management actions for your lab notebooks. An illustrative example of a lab notebook policy from GR-based innovation initiatives is contained in Annex A.

What do laboratory notebooks look like? An illustrative example of a lab notebook policy from GR-based innovation initiatives is contained in Annex A. The front cover of the Notebook should show a description of the content in it (for example: project name, main activity), the starting date and the last dates of entry in the book. Essential items need to be recorded *in ink* or another *permanent medium* as follows.

- a detailed account of every planned and executed experiment which you have done. It should show details enabling a researcher or another person skilled in art of GR characterization, innovation and research to determine the phases of what was done, why it was done, and what the *results* were;
- the dates of each entry, along with the account or record;
- copies of, or references to, your protocols, laboratory consumable supplies, lot number of entries, description etc.;
- explanation of the significance of each experiment and results;
- details of each experiment;
- personal comments could motivate you;
- all taken photographs, data written in it, data in file of computer. Record the file location in the notebook;
- cross references, you may use reference of the earlier information instead of re-writing;
- use pre-printed forms to save time if the experiments involve standard procedure;
- all information related to data should be captured (the data should be backed up and archived).

Laboratory notebooks should normally be kept confidential, thus store them in safe places and report any loss. If the creation or maintenance of trade secrets is a part of your IP strategy, please see the relevant chapters of this Guide for the 'reasonable steps' for the maintenance of secrecy which you should take in order to integrate the lab notebooks as part of the implementation of a trade secret protection program.

In the context of research collaborations, including characterization partnerships, a laboratory notebook policy is an important tool for synchronizing and coordinating your research and development partnerships. A merely illustrative example of a laboratory notebook policy is presented in Annex A.

b) Invention disclosure forms

From a patent strategy point of view, it is best practice to disclose an invention as soon as it *is* an invention. The policy objective of the patent system is precisely to establish an incentive structure through the availability of patent rights which makes this the most rational and self-interested choice of the innovator to disclose his invention – thereby making it available to society at large as a basis for further innovation. Conception of an invention may occur over a long period of time. Conception of an invention in patent law means neither 'to have an idea' in some kind of 'Eureka!'-moment, nor does it require to reduce an invention to practice. Thus, in your GR characterization and innovation work, you might conceive inventions over a longer period of time, depending on the circumstances.

Once an invention has been conceived, an invention disclosure form should be completed as soon as possible. To ensure that invention disclosure forms are filled, effective IP education programs should be conducted to train researchers and scientists, and the WIPO TK Division offers training programs and, together with the WIPO Academy, a distance learning course specifically for IP and GRs in the life sciences. You might wish to sign up multiple team members of the GR characterization and innovation team for such training. In the case of GR-based inventions, WIPO's TK Division provides such training in cooperation with the Swedish Patent and Registration Office through the ITP on IP and GRs in Support of Innovation.

When you disclose an invention in an invention disclosure form, you should not only try to describe the details of the invention, but also how the invention may relate to other inventions as part of a

portfolio. This wider context will determine both your research plans and when it is most effective to file your patent applications, if any.

In case of collaborative GR characterization and research projects, the collaboration projects are often structured through research collaboration contracts, grants or broader inter-institutional agreements, such as Memoranda of Understanding or Cooperation. For relevant IP and ABS clauses in such collaboration contracts and inter-institutional agreements pertaining to GRs and GR data, you may find them in the WIPO TK Division's Online collection of ABS contracts. These agreements include provisions which set out arrangements for co-ownership of IP or co-inventorship for inventions developed collaboratively during the term of the agreement. Before you make assumptions about the ownership of inventions resulting from joint GR characterization or innovation work that you are doing with your partners, you should closely study the applicable agreements and then consider the implications for IP ownership. Depending on the provisions in such agreements, you may need to notify your partners institution upon receipt of an invention disclosure form from your team and before the filing of a patent application. In either case, it will be useful to complete an invention disclosure form.

Practical Tip

When you have conceived an invention resulting from your GR characterization and innovation work, you should complete an invention disclosure form, which discloses the invention, the inventor(s) and the data of invention. Even if you will not file a patent application for the invention, a completed invention disclosure form may to some extent protect against subsequent patent applications filed by other parties that might prevent you from practicing the invention that you have invented. In general, it is advisable to establish an invention disclosure policy for your GR characterization and innovation work overall. An example of the typical information content of invention disclosure forms is available at Annex B.

2. Copyright management processes

As seen in chapter IV.A.1(d), in addition to the patentable subject matter, it is an important to continue to manage copyright in your characterization work. For this it is best to maintain a copyright log as a part of your administration of your project. This will help you to make sure that you can publish your characterization results along with all related information when you wish to do so.

For example, in the course of your GR characterization project it is likely that you will, at some stage, wish to release parts of your characterization and research results for purposes such as:

- presenting your results to, and receiving feedback on them from, a general audience (i.e., publication);
- disclosure of your results to donors and in the context of donor reporting or other reporting obligations (i.e., reporting);
- the exploration of commercial potential of your results.

At that stage, from an IP perspective it is important that you can easily:

- pinpoint all the third-party copyright material;
- specify for each piece of copyright material whether you have permission or licence to use the material; and, if not,

- determine if that material is important for you for the publication of your characterization results.

Practical Tip

In order to keep track of the copyright material which you might use in the publication of your GR characterization results, you may wish to keep a copyright log of the proprietary material that you are using in your work and that you would use in your research publications. An example of a standard copyright log is available at Annex C.

If you find that you need to obtain another right holder's permission to use certain copyright content and there are no exceptions which apply to your use in the exercise of copyright by that right holder, you will need to obtain copyright clearance for your use of the material.

Depending on the exact context, you may consider these steps to obtain permission for the relevant copyright material:

- verify whether there is a copyright license statement or permission statement on the material, the use of which you are seeking permission for. If it is copyright protected datasets from a database or repository, you should verify these terms for that database or repository;
- determine whether that copyright license or permission statement covers the uses you intend to make of the concerned material;
- if there is no information on copyright ownership or you can, for any reason, not determine it, an important alternative possibility is to contact the publisher and request rights holder details and ownership information from them;
- once you have been able to identify the copyright owner, you should request permission to include their proprietary material in your work in a copyright permission request letter;
- once you have been granted permission to use the copyrighted material, you might wish to give acknowledgement to the permission in your research reports and results.

When you send a permission request letter, you should ensure that you include a description of a number of items, such as the copyright material which you are requesting to use, how you are requesting to use it, and the request itself for the owner's permission to use the material. Some of the elements to reflect in your permission request letter include:

- the right holder's details;
- your own details (name, contact details, institutional affiliation, as applicable);
- the details of your institution (name, contact details);
- a specification of the material you intend to use and the source from which you are retrieving it, including the amount, page numbers, data set IDs, book chapters, etc. Depending on the extent of the material, you might wish to attach a copy of it;
- the uses you intend to make of the material, i.e. for integration into databases, e.g. INSDC or your own, if it concerns datasets, or journal articles, book, report, etc, if it concerns texts;
- how you intend to make the material available e.g. making it publicly available in the digital environment through public, institutional repositories, such as INSDC; making it available only internally to your research team or institution (e.g., in your own GR databases or on the intranet); as a prior art reference used in a patent application, etc.;
- what kind of license you are requesting and the duration of the permission that you are requesting. For example, as applicable, you may wish to specify if the license you are

requesting is permanent or time-limited, irrevocable or revocable, exclusive or non-exclusive, for local, national or worldwide use, etc.;
- if you intend to make any changes to the material, add annotations to it, or make selections that might have the effect of changing the material, you should specify this;
- Emphasize that the work of the right holder will always be referenced and acknowledged. You might also wish to ask the right holder how they wish to be acknowledged;
- a request to the right holder to confirm that they are the owners of the material and that they agree by return letter or email with your requested use.

For the course of your GR project, it is preferable that you receive the right holders' permission in writing, but it does not matter whether it is by email or in hardcopy.

3. Trade secrets and the protection confidential information

As data get generated during the characterization and innovation process, which you may subsequently wish to protect as undisclosed information, including as trade secrets, it is critical that you already take 'reasonable steps' to keep them undisclosed and secret as early as during characterization itself.

For this you might wish to take the following set of "reasonable steps" which are generally considered as good practice in maintaining trade secrets and protecting confidential information.

- *Trade secret protection policies and procedures*
  - apply the institutional, staff and third-party policies continuously, as developed during Part IV above;
  - apply marking and segregation procedures: routinely apply confidentiality marking, segregation and storage procedures for your trade secrets;
  - continue to apply standard confidentiality clauses in all service provider, employee, contractor, supplier and other relevant third-party agreements. For examples of such clauses see the WIPO Online collection of GR agreements of the WIPO TK Division and conduct a search for "confidentiality" or "trade secrets";
  - Routinely conclude NDAs for all additional collaborations: adapt and conclude your NDAs for any additional collaborations you might engage in during the characterization process and in which you are disclosing your defined trade secrets or protected undisclosed information;
  - Trade secret inventory and related documentation: As your GR data and research results accumulate during your characterization and innovation work, keep written records of all your trade secret-related activities, including use, disclosure and management of the trade secret protected subject matter;
- *Confidentiality and information management*
  - Maintain 'need to know' access during GR characterization: if you have identified certain parts of your GRs, GR data and the characterization and innovation work on them as confidential, segregate those parts of the work and limit physical and IT access to genetic material and data for individuals, groups and departments on a 'need to know' basis;
  - Use IT access measures, such as secure password logins, multiple keys, firewalls, etc.
  - Use IT technical measures: if necessary to maintain necessary confidentiality of your GR databases or other GR data records, use technological measures such as encryption, email restrictions, anti-virus and anti-malware software;
- *Risk management measures*

- Maintain your trade secret inventory: depending on the scale of your GR characterization work and the GRs and GR data you are managing, maintain an inventory of key trade secrets which you have established before the characterization work began;

- *Third party management measures*
  - Written NDAs and other agreements with third parties: when entering research collaborations or procuring sequencing-, IT- or other services for your GR work, ensure that all service agreements and supply chain agreements address the necessary confidentiality issues in sufficient detail and refer to your trade secret policies and procedures;
  - Clear third-party communications: clearly and up-front communicate your expectations and policies regarding trade secret protection to any service providers, suppliers, contractors, new employees or other parties you engage with during the characterization phase.

Practical Tip

During your GR characterization work maintain reasonable steps for the protection of trade secrets and confidential information which you have initiated before characterization, including your trade secret protection policies and procedures, confidentiality and information management, risk management measures and third-party management measures. For examples of relevant confidentiality clauses for GR- and GR-data related contractual agreements such as MTAs, MAAs, NDAs, ABS agreements, license agreements, etc, see the Online collection of GR agreements of the WIPO TK Division on the WIPO website.

VI. AFTER GENETIC RESOURCES CHARACTERIZATION

As with the stages before and during the characterization process, you can manage your interfaces between genetic material and data and between IP and other rights and obligations in two simultaneous and complementary levels: (1) taking into account legal considerations when managing your GR subject matter (material, data, databases, and, at this stage of the process increasingly also other abstract objects which will emerge from your characterization work, such as alleles, sequences, traits they code for, etc.); and (2) taking into account subject matter considerations about your characterization results in the management of your IP and other rights and obligations, and your related strategies. As with previous chapters we will review these consecutively, starting from the subject matter of GR and GR data.

A. GR data and information management

Once your sequencing work has generated genetic sequence data or amino acid sequence data, it is very important for you to manage these growing data sets in an IP-friendly format *from the beginning*, in order to save labor-intensive conversion to IP formats at a later stage.

WIPO has developed international standards for the handling of genetic sequence data for many years and the relevant *Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications* (ST.25) has been revised.

As a first step it is suggested that you apply the relevant WIPO Standards from the outset to your management of the nucleotide and amino acid sequence data that result from your GR characterization work, in particular if you consider filing patent applications at a later stage.

a) Standard ST.25

WIPO elaborated this data standard in the early 2000s in order to provide standardization of the presentation of nucleotide and amino acid sequence listings in international patent applications. The Standard allows patent applicants to draw up a *single* sequence listing which is acceptable to all relevant patent-granting authorities, including Receiving Offices, International Searching and Preliminary Examining Authorities for the purposes of the international phase, and to all designated and elected Offices for the purposes of the national phase under the PCT. The Standard enhances the accuracy and quality of presentations of nucleotide sequences given in applications to make for easier presentation and dissemination of sequences for the benefit of patent applicants, like yourself, the public and the patent examiners, to facilitate searching of sequence data and to allow the exchange of sequence data in electronic form and the introduction of sequence data onto genetic sequence databases. WIPO member states agreed that Standard ST.26 be used from January 1, 2022 at national, regional and international levels instead of ST.25.

WIPO products and services: When managing nucleotide sequence data resulting from your GR characterization and innovation work, you can apply the *WIPO Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (ST.25)* to your data sets so that you can:

- draw up a single sequence listing for your patent applications which will be acceptable to all relevant PCT patent-granting authorities, including during the international and national or regional PCT phase and procedures;
- enhance the accuracy and quality of your presentation of your sequences for easier dissemination;
- facilitate searching of your sequence data; and
- allow your sequence data to be exchanged in electronic form and introduced into the best and largest sequence data repositories in the world.

For your easy and direct reference, you can download the WIPO Standard ST.25 directly from the WIPO website at WIPO Handbook (https://www.wipo.int/standards/en/part_03_standards.html) or at the WIPO TK Division as part of the hands-on tools to manage your genetic sequence data yourself.

b) Standard ST.26 (and its revision)

WIPO has also developed a *Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (Extensible Markup Lanuage) (ST.26)*. This Standard defines the nucleotide and amino acid sequence disclosures in a patent application required to be included in a sequence listing, the manner in which those disclosures are to be represented, and the Document Type Definition for a sequence listing in eXtensible Markup Language (XML). It has been recommended that industrial property offices accept any sequence listing compliant with this Standard filed as part of a patent application or in relation to a patent application from January 1, 2022.

In order to be assigned its own sequence identification number, your sequence listing must not include sequences having fewer than ten specifically defined nucleotides, or fewer than four specifically defined amino acids.

ST.26 establishes the requirements you would need to meet for the presentation of your nucleotide (or amino acid) sequence listings of sequences when you disclose them in your patent applications. A sequence listing complying with the Standard contains a general information part and a sequence data part. You need to present your sequence listing in a *single file in XML* using the Document Type Definition (DTD) contained in Annex II of the Standard. The purpose of the bibliographic information contained in the general information part is for association of the sequence listing to the patent application for which the sequence listing is submitted. The sequence data part is composed of one or more sequence data elements each of which contain information about one sequence itself. The sequence data elements include "feature keys" and subsequent qualifiers based on the International Nucleotide Sequence Database Collaboration (INSDC) and UniProt specifications.

For the purpose of ST.26, a sequence for which inclusion in a sequence listing is required is one that is disclosed *anywhere* in an application (claims, description or other parts) by enumeration of its residues. For the purposes of your patent application, you can represent the sequence as an unbranched sequence or a linear region of a branched sequence containing ten or more specifically defined nucleotides, wherein adjacent nucleotides are joined by (i) a 3' to 5' (or 5' to 3') phosphodiester linkage; or (ii) any chemical bonds that results in an arrangement of adjacent nucleobases that mimics the arrangement of nucleobases in naturally occurring nucleic acids.

In 2021 WIPO's Committee on WIPO Standards (CWS) approved version 1.4 of a WIPO Standard ST.26 "Recommended standard for the presentation of nucleotide and amino acid sequence listings using XML (eXtensible Markup Language)".

c) Applying WIPO Sequence

In order to support the use of ST.26 at national, regional and international levels, WIPO has developed a common software tool, i.e., WIPO Sequence, to enable patent applicants around the world to prepare sequence listings and verify that those sequence listings are in compliance with WIPO Standard ST.26. It is also developing complementary software for patent-granting authorities to verify sequence listings submitted by applicants. One of the objectives of the tools is to support a smooth transition from WIPO ST.25 to ST.26 for national and international patent applications referring genetic sequence data, when ST.26 enters into force in January 2022. The tool enables you to import a sequence listing in ST.25 format and transform it to ST.26 format so that you can reuse prior data in ST.25 format for a new patent application in ST.26 format.

We are pleased to inform you that you are welcome to download and/or use WIPO Sequence to manage your genetic sequence data yourself from the WIPO Sequence webpage or, alternatively, a hyperlink on the one-stop Service tile for IP and GR rights management of the TK Division.

WIPO products and services: In order to help you to prepare your sequence listings for your patent applications and verify that those sequence listings are in compliance with WIPO ST.26, you can use the *WIPO Sequence* software tool. You can download and use the WIPO Sequence from the WIPO Sequence webpage or, together with other GR rights management tools, by a hyperlink on the Service tile on IP rights management of GRs and GR data of the WIPO TK Division website.

2. Data and information sharing

WIPO's work on IP, GRs and GR data that pertains to nucleotide sequence data is consistent with, and has wherever possible been developed in coordination with, the International Nucleotide Sequence Database Collaboration (INSDC). This is because INSDC is a long-standing foundational initiative on nucleotide sequence data, which covers the full spectrum of raw reads, through alignments and assemblies to functional annotation, enriched with contextual information relating to samples and experimental configurations. INSDC operates between the world's major nucleotide sequence database providers, DDBJ, EMBL-EBI and NCBI.

After characterization of your selected GRs and the generation of nucleotide sequence data, if you have decided not to patent potential resulting inventions or maintain those sequence data or related information or know-how as a trade secret or protected undisclosed information under sections IV and V above, and if you are opting for technical public disclosure of the sequence data as your preferred rights management option, an option is to upload the resulting data into INSDC sequence databases, in order to make the data as widely available as possible and for them to be searchable by other researchers and innovators as well as recognized by patent examiners for purposes of search and examination.

a) Uploading to INSDC databases

By using the WIPO suite of rights management tools for GRs and GR data to manage your nucleotide sequence listings, you can control and undertake certain aspects of your practical rights management work for your sequence listings yourself. One rights management option in this regard, is the technical public disclosure of the sequence data. As for nucleotide sequence databases for disclosing your nucleotide sequence listings, an option is the nucleotide sequence databases of INSDC.

With the TK Division's rights management tools for IP and GRs, you can bring your sequence data automatically into compatible format for you to be able to upload it to INSDC member databases. This requires multiple worksteps and you can undertake them for your own nucleotide sequence data with the resources available at the one-stop service tile for GRs and GR data rights management on the TK Division's website.

For full details of how to submit data to the INSDC databases please see the practical tool for technical public disclosure which forms part of the wider IP toolkit on the rights management service tile. Please select the upload instructions of a collaborating partner database, GenBank, ENA or DDBJ, and consult the DDBJ/ENA/GenBank Feature Table Definition for submitting your data to INSDC partners. The overall goal of the Feature Table design is to provide an extensive vocabulary for describing features in a flexible framework for manipulating them. The Feature Table documentation represents the shared rules that allow INSDC databases to exchange data on a daily basis.

The range of features to be represented is diverse, including regions which:

* perform a biological function,
* affect or are the result of the expression of a biological function,
* interact with other molecules,
* affect replication of a sequence,
* affect or are the result of recombination of different sequences,
* are a recognizable repeated unit,
* have secondary or tertiary structure,

* exhibit variation, or have been revised or corrected.

Access to INSDC databases is free-of-charge, unrestricted and open to any member of the public. This enables you and other researchers and innovators to access data, plan their experiments and analyze their results together with existing data. As original scientific contributions, data deposits form part of the scientific record and are citable in the literature. You can also correct and update your deposited data anytime. Moreover, many scientific journals demand a database accession number as a condition of publication of an article.

Additional resources, tools and references: If, after your GR characterization work, you have decided not to patent potential resulting inventions or maintain the nucleotide sequence data resulting from your GR characterization work, or related information or know-how, as trade secrets or under protection of undisclosed information, you can opt to make a technical public disclosure. You can use the one-stop IP-GR rights management service tile for references to the steps of a legally certain technical public disclosure. If you decide to make a technical public disclosure, an option is to submit your data to the INSDC databases. To submit and upload your data to INSDC participating databases, please see the Feature Table of INSDC and the upload instructions of the INSDC database providers.

B. Legal strategy and integrated rights management

As before and during the characterization process, you may wish to take a holistic approach to your work by ensuring that your rights management approach after characterization: (a) integrates your management of the physical material and intangible assets, including IP assets, in a holistic manner and (b) that it combines IP rights and related rights management for the outcomes of your characterization work. Furthermore, ideally, your rights management approach and legal strategy would be a continuation, update and concretization of the approach and strategy which you have already developed before and during characterization.

This section provides you with additional information which becomes relevant at this stage so that you can continue and concretize your IP management as you continue to innovate by optimally leveraging the results of your work within the legal frameworks that are applicable to your GR characterization outcomes and the downstream innovation pathways based on them.

1. Freedom to operate (FtO)

When you are considering your FtO to develop, make and put on the market a new product or process resulting from your GR characterization and innovation work, an FtO analysis is done by systematically and fastidiously disaggregating the product or process into its basic constituent elements and then analyzing each one for the attached IP or other rights which could constitute encumbrances for future product(s) or process(es).

If you have identified results of your GR work, which you would like to develop into a product or process for production, then a thorough FtO analysis will inform you and your institution whether the development and commercialization of the new product or process can go forward with a limited risk of infringing unlicensed IP or other GR-related rights of others.

However, since the IP and other legal landscapes surrounding your GR characterization results are continuously changing and evolving, the outcomes of your FtO analysis may also change and need

to be updated over time. New patent titles might be granted or old ones expire, or some might be invalidated; patent portfolios or parts thereof may be transferred, assigned or licensed; licenses may be issued and terminated. All these developments continuously change your FtO.

Get legal advice: for a customized freedom-to-operate analysis it is important to seek advice from a patent counsel before you finalize your decisions and R&D strategy for embarking on the development and production of a new GR-based product or process.

An FtO analysis is a systematic and thorough exercise, which should be completed by specialized counsel. However, several steps can be well prepared. Some of the preparations that you can do at this stage include:

- Composing your team for FtO analysis
- disaggregating and analyzing the product or process to be developed
- compiling and using your laboratory notebooks and other materials
- assessing GR pedigrees
- interviewing the GR researchers and scientists
- identifying relevant contractucal agreements, such as MTAs, shrink-wrap licenses, and other contracts concerning the GRs and related property titles
- defining FtO questions and issues
- selecting patent literature and non-patent literature databases
- dealing with sectorial specific information resources for pharmaceutical patent information
- managing the ‘grace period’
- ensuring due diligence during the FtO analysis and beyond.

2. Positive IP strategy

Your positive IP strategy after the characterization process ideally is a furtherance of the IP strategy and management measures that you have already developed and put in place before and during your GR characterization initiative. This section provides you with IP-specific considerations for the results of your work within the same categories as the previous Parts IV and V (namely, patents, copyright and trade secrets), in order for you to be able to leverage the innovation you have generated or can generate, based on your GR characterization work.

a) Patents

Within the criteria set out in section IV.A.1(a) above, patents are in principle available for a wide range of subject matter that might result from your GR characterization work. In section IV.A.1(a), you reviewed the scope of patentable subject matter in relation to GRs and the patentability criteria which apply to GR-based inventions falling within that scope. In general, GR-based inventions within this scope might, typically and *inter alia*, relate to:

- Small molecules and low molecular products
- Nucleic acids
- Proteins
- Antibodies
- Micro-organisms

- Plants
- Animals
- The human body and parts thereof (excluded from the scope of this Guide).

For reasons of brevity and substantive focus, this section only covers inventions within the category of nucleic acids and their sequences. This is in keeping with the overall focus of the Guide on *genomic* sequence data as a subset of GR characterization data. Nevertheless, it is important to recognize that other categories of inventions, *especially proteins* and their amino acid sequences, are closely related to your nucleic acids sequencing results and such inventions may also likely be outcomes of your GR characterization work. You should accordingly *think broadly* about possible patentable inventions arising from your work. For further reading on the wider categories of inventions that might follow from your characterization work, please see the relevant literature on the patentability of proteomic and other biotechnological inventions.

For the purpose of Part VI we will maintain the *genomic* focus which was already introduced in Part IV (Before Characterization) and Part V (During Characterization).

In Part IV, you reviewed the criteria and limitations of the basic subject matter within which patentable inventions might arise from your GR characterization work in general. This gave you a sense of the outer limits and inherent requirements of GR-based innovations which might potentially be or become patentable inventions.

Based on that delineation of the outer limits of patentability and the results of your actually conducted characterization work, in this present Part VI you can now think concretely about which specific patentable inventions within that afore-delineated scope of GR-based subject matter you might be able to claim in potential patent applications and how your patent claims for those inventions could be constructed.

The purpose is for you to think about which patentable inventions you can identify within your research- and GR characterization-results, and how you could claim those patentable inventions in potential patent applications. For this initial identification, you may rely upon your Laboratory Notebooks and the Invention Disclosure Forms which you have created based on Part V of this Guide.

However, your initial identification of patentable inventions and the decision to actually file patent applications are by no means identical and numerous additional considerations concerning your research strategy, general IP policy, business model, commercial strategy, public goods objectives, market potential, competitors, etc., should be taken into account when making your decisions whether, when, where, how and for which inventions to actually file patent applications. Whether you would then *actually* file patent applications and prosecute a strategic patent portfolio based, *inter alia*, on your GR characterization outcomes, is another question, which will depend on your business model and which you need to consider separately. As set out above, such considerations lie beyond the scope of this Guide, but information resources on patent strategy for GR-based inventions are available. If, based on such considerations and literature, you reach a decision to file patent applications, you should obtain specialized legal advice for drafting your patent application.

Get legal advice

If you have decided to file patent applications, you should seek specialized legal assistance in conducting prior art searches, drafting the application, including claims and

description and in mapping out your patent prosecution strategy, nationally and internationally, in synchronicity with your overall research and business strategy.

Now you can start thinking about the kind of patentable inventions that result from your GR characterization work, which you could consider filing patent applications for, and about how you could claim those inventions.

As a general baseline, the patentability of nucleic acids is determined according to established patent principles in the field of chemistry. This is because nucleic acids are chemical compounds in the meaning of patent law. Polynucleotide molecules, which are defined by their nucleic acid sequence and code for different proteins, are structurally distinct chemical compounds.

The nucleic acid sequence within these polynucleotide molecules is referred to as “nucleotide sequences”. In patent law, nucleotide sequences normally constitute independent and distinct inventions according to the practice of many patent-granting authorities. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement applicable for divisional patent applications.

Within international ABS frameworks, the order of nucleotides found in the polynucleotide (DNA or RNA) is defined as the “genetic sequence” of the GR (PIP Framework, Art. 4.2). In general, a description of the genetic sequence is the result of genomic characterization of the GR. A *list*, which lists this genetic sequence of the polynucleotide, represents the nucleotides through standardized symbols, fulfils certain additional, minimum length requirements and which gives a detailed disclosure of the nucleotide sequences and other available information is defined as a “sequence listing” in the international patent system by WIPO ST.25 and ST.26.

The data compiled in such “sequence listings” of genetic sequences of GRs are referred to in aggregated form as “genetic sequence data” (GSD). GSD constitute a subset of what is described in this Guide as “GR data” (which additionally includes other characterization data of GRs, such as proteomic, metabolomic, phenomic and other omics characterization data about GRs).

Most nucleic acids claimed in patent applications contain a coding region, i.e. a stretch of DNA or RNA which is subject to transcription and/or translation processes, resulting in generation of a RNA or protein. The sequence of a given nucleic acid determines the primary sequence of the immediate expression product, such as a protein, which later may be further processed post-translationally. A protein sequence could correspond to a multitude of nucleic acid sequences coding for this sequence, only one (or a few) of which will occur in nature. This is the beauty of the genetic code: it is degenerate, but unambiguous. Therefore, the known relation between amino acid sequences and corresponding nucleic acid sequences is a peculiarity in the field of inventions concerning nucleic acids (and proteins).

Descriptions of genetic sequences in various formats are one probable output of your GR characterization activities (these descriptions range from initial raw sequence reads to fully annotated and genotyped genetic sequences). Now that you have the nucleotide sequences characterized in a more advanced and value-added manner, you can begin to consider the kind of patentable inventions that might result from your work and how you could claim those inventions.

Generally speaking, nucleic acids of GRs are claimed in patent applications through product and process claims, which could be described through the following categories:

1. *Product claims for nucleic acids*
    a. which characterize a nucleic acid by the nucleic acid sequence itself (in full or in part);
    b. which characterize a nucleic acid by functional terms;

c. which characterize a nucleic acid by the amino acid sequence of the encoded protein (in full or in part);
d. which characterize a nucleic acid by reference to a deposited microorganism or deposited DNA;
e. which characterize a nucleic acid by parameters;
f. which characterize a nucleic acid by a process for its preparation;
g. which comprise nucleic acids as essential elements;
h. for certain types of nucleic acids and methods of using same;

2. *Process claims for nucleic acids*
   a. involving isolation from a nucleic acid source;
   b. claims involving genetic engineering or synthesis;
   c. Use claims/purpose-limited product claims for nucleic acids.

Most often patent applications for nucleic acid inventions contain a combination of multiple categories of such claims.

b) Copyright

As reviewed in section IV.A.2, copyright protects original works and the data of raw sequencing reads are usually not copyright protected. However, if you have developed advanced and complex annotations of your nucleic acid sequences, which by virtue of their originality, might qualify for copyright protection, there are a few standard and basic copyright management measures that you might wish to take when publishing your works, including scientific articles describing your GR characterization outcomes, original software code or even original annotated sequence listings or compilations thereof.

If you publish scientific reports, articles or books containing your sequence data, those literary or scientific works will be copyright protected (however, of course, not the genetic sequence data as such). Furthermore, *if* your compilations of advanced, annotated data qualify as protected compilations in the meaning of copyright law, they would also be copyright protected.

In such cases, *if* certain outputs of your GR characterization initiative qualify for copyright protection, you may wish to ensure that a copyright notice (in form of the © sign) is added when the works or compilations are published. Even though the copyright notice it not required as a condition for copyright protection in countries which adhere to the Berne Convention, it is still useful to do so, since a copyright notice would make it easier to prove in case of copyright infringement that the infringement was wilful. This may be particularly relevant in cases of compilations which may not be obviously copyright protected and where innocent infringement could otherwise be claimed. Adding a copyright notice might also have the effect of deterring potential infringement and protecting your work also in countries which do not adhere to the Berne Convention (though these are very few).

Practical Tip

If any of the outcomes of your GR characterization and innovation work form copyright protected subject matter, whether it is scientific articles, books, data compilations, software code or advanced annotated sequence data compilations, it is advisable to place a copyright notice (the © symbol), with the year of publication and the copyright owner's name on the publication.

The copyright notice should include three elements: the © symbol, the year in which your work is published, and the name of the copyright owner. The notice should be included on your work when

you first publish it and on every edition that you publish subsequently. 'Publication' in the meaning of copyright occurs when your work or compilation is made generally available to the public by the copyright owner or others acting with the owner's permission (e.g., the publisher of a scientific journal or a database operator).

If you publish a new version of an earlier publication of yours, the notice does not have to contain the dates of the earlier version or versions, even if your changes to the earlier publication make it a new version for copyright purposes. Nevertheless, it is common practice to include such dates of earlier editions or versions in a copyright notice.

Additional Resources

For further copyright management references, please see 'Further reading' on the WIPO TK Division website. The copyright references include further resources, toolkits, how-to-manuals and practical information resources.

c) Trade secrets and protection of undisclosed information

Even after you have completed your GR characterization and annotation work, you should perpetually maintain your reasonable steps for the protection of your trade secrets and confidential information related to your resulting GRs and GR data.

At this stage these steps or measures might additionally include*, inter alia*:

- *Security management for your GR research and innovation results*
  - Additional security systems for your GR research and innovation results should ensure that the confidential GRs and GR data resulting from your characterization and innovation work are not left unattended, disseminated in the excitement of scientific discovery, or can be easily seen or removed by visitors or unauthorized third parties in your laboratory.
- *Enhanced risk management in case of high-potential, confidential GR research results*
  - (re)assessment of severity of risks: now that you have a more complete understanding of potential, value and confidentiality of the results of your GR characterization and innovation work, assess again, in light of the additional information, which trade secrets might be taken, used or disclosed without authorization, why and by whom.
  - Enhanced risk mitigation plan, if necessary: please make sure you categorize and rank the (re)assessed risks and develop or enhance your risk mitigation plan to address the new or increased risks you have identified. Update and review this mitigation plan and its implementation at regular intervals;
  - Training and corporate culture: provide training for all your relevant staff to remember the importance of trade secret protection which was set out in the introduction of this Guide.

Practical Tip

Even after you have completed your GR characterization and innovation work, *never ever* stop to implement and remain vigilant about your reasonable steps for the protection of trade secrets and undisclosed information for those results of your GR work which you have decided to protect through this tool. Only stop to take those steps if you decide that you no longer wish to maintain such information or resources as a trade secret.

VII. CONCLUSIONS

This Guide is only one element of the IP management toolkit for GRs and GR data. A wider suite of practical tools is the main vehicle by which the WIPO TK Division delivers integrated and practical rights management services for GRs and GR data in the form of practice-oriented information resources, hands-on tools and related support services. Its intended audience are those innovators who directly work with GRs and GR data at a, primarily molecular, technicallevel.

If the current Guide addresses the IP aspects of GRs and GR data from a different angle than the one you are looking for, it is recommended that you review the other elements of WIPO's broader IP toolkit that are available on the TK Division's service tile for IP management for GRs and GR data. If the Guide has been useful to you and you wish to have more IP information at the technical level at which the current volume describes IP and GR characterization work, it is recommended that you consult the further reading materials, practical tools and case studies which are available on the service page of the WIPO TK Division and other WIPO Programs. Any feedback and comments on the present volume may also be forwarded to the TK Division at grtkf@wipo.int.

VIII. ANNEXES

A. Sample laboratory notebook policy

This Annex provides a summary of an illustrative example of a laboratory notebook policy. This example is provided exclusively and only for illustration purposes. It contains a summary of a sample document adapted and prepared by some change projects of the WIPO-Swedish Patent and Registration Office's International Training Program on Intellectual Property and Genetic Resources in support of Innovation, based on a document originally prepared at Cornell University for its collaboration with the International Agricultural Research Centres of the Consultative Group on International Agricultural Research. The policy has been adapted to reflect the specific requirements of public sector research institutes and the change projects in the afore-mentioned program. It can serve only as an illustrative example here, not as a template for your own policy. For your own policy please seek individual and customized legal advice.

Sample Laboratory Notebook Policy to Protect Invention

The purpose of this policy is to ensure that the institution is sufficiently protecting its inventions, research, resources and products, so that discussions and potential allegations during disputes or litigation are based on documented facts. This includes such items as the date of the making of an invention or the generation of data sets or a description of the invention or research or data sets, the dates of research or characterization techniques that were used, and the like. In order to do this, the laboratory notebook, in whatever format, must be an honest representation of the research and characterization work done by the institution, and must be acceptable to a court, to the relevant patent-granting authorities, and other offices whose charge is regulating statutory protection of IP or related branches of law. Therefore, certain standards apply to each type of notebook.

GUIDELINES

General

All ideas and data must be entered into the laboratory notebook. Entries must be complete enough that another scientist would have little or no difficulty understanding and repeating the experiments or characterization work. Every page must be signed, and dated each day, by the scientist running

and recording the experiment, and signed and dated by a witness, if not immediately, then at least within one week of the scientist's signature.

In deciding the exact procedures to follow, the laboratory notebook must reflect its own integrity and corroborate information independent of the person doing the research.

The laboratory notebook must reflect a clear and accurate representation of activities that have taken place in the lab and that none of the information has been falsified: any changes made to the recorded information should be clear and obvious and the new information should be able to be compared with the old; and the notebook should be completely intact, with no pages missing or illegible. A witness who has not been involved in the experiment, by signing and dating the notebook, must attest (by virtue of signing) that the information, experimentation, characterization and/or ideas that occurred were recorded on the date indicated.

Categories of notebooks

A. Hardbound notebook

Laboratory notebooks are checked out from the designated librarian in the department or office specified and returned to the designated technician immediately upon being filled, to be scanned and saved.

- When signing out a new laboratory notebook, the laboratory notebook should be numbered, permanently bound, have index pages and all pages should be pre-numbered.
- The researcher should enter a new experiment or characterization process in the index each time a new experiment or characterization process is started.
- Each page should be used in order. No blank pages should be left between experiments or characterization processes.
- Enough information should be recorded so that a scientist "skilled in the art" of molecular and phenotypic GR characterization techniques could pick up the laboratory notebook and easily determine what had been done, why it had been done, and what the results were. Entries should include procedures, reagents, GR specimen accession numbers, lot numbers, GR database access logs, where appropriate, sketches, descriptions, and, in the case of field trials, field and plot numbers, etc. The purpose and significance of the experiment or characterization process as well as observations, results, and conclusions should be made clear. What may seem trivial or obvious at the time experiments or characterization processes are conducted, may later be of critical importance.
- If procedures have already been described in an earlier experiment or characterization process or have used a standard protocol, and the researcher has not deviated from the previous descriptions of the experiment or characterization process for the current one, the researcher may reference earlier information instead of writing it out again (for example, if the researcher was starting a new experiment or characterization process on page 42, and was using the same protocol as already described on page 25, he or she could write on page 42, "Following the protocol as described on page 25 of this laboratory notebook").
- All data should be entered, in ink, directly into the laboratory notebook.
- Corrections should be made by drawing a single line through the entry. Erasers or whiteout should never be used. The researcher should initial each lineout, and if possible, add next to each lineout a note of explanation, such as, "*wrong data*." The researcher should never tear pages out of the laboratory notebook. Pages may be copied for the researcher's own use, but not removed.
- At the end of each day the researcher should put a line or a cross through any unused space on that day's page(s) in the laboratory notebook. If a blank line is left between paragraphs, there is no need to lineout the one line, but if a number of lines have been left at the bottom of the page,

they should be marked through. This could prove it was impossible to enter additional information in the laboratory notebook, in those empty spaces, at a later date.

- If additional information, such as machine-generated sequence listings, tables or graphs, original photos, or short reads, are part of the experiment or characterization process and are small enough to be attached in the notebook, the information should be attached using a permanent adhesive or non-removable tape. The researcher should sign his or her name over the border of the attachment, crossing over onto the laboratory notebook page. Signing in this way would clearly show, if at any time in the future the attachment had been removed.
- If the additional data is too large for the laboratory notebook (for example, a digital sequence listing printout that is a few pages long), such additional data can be signed and dated; countersigned and dated by the witness; and given an appropriate ID number. The researcher should note on such additional characterization data or other data sets in which laboratory notebook and which page number the additional data is referenced. Then, in the laboratory notebook the researcher should reference the additional characterization data's ID number and note the secure-storage location where the additional data is being held. Preferably, a drawer with a set of files that are always used to store oversized information should be used. A summary of the GR characterization data or other data can be placed in the laboratory notebook. The same sort of procedure should be followed with any GR data samples that are to be kept.
- Each original page of the laboratory notebook must be signed and dated by the researcher and by a witness. A witness should be someone who has read each entry, who is competent to understand what she or he has read, but who is not a co-inventor. Each research group should designate a person who is responsible for assigning permanent witnessing partners. However, if the assigned witness is not available when needed, another person who fulfils the appropriate criteria may stand in.
- If any changes are made after pages are signed or witnessed, the changes must be initialled and dated by both the researcher and a witness. Care should be taken to use the current date when signing or witnessing a laboratory notebook.
- Ideas should be recorded in the laboratory notebook, as these may be important in determining a date of invention.
- It is important to return completed laboratory notebooks to the designated person as soon as possible to ensure a duplicate copy of the laboratory notebook is captured by scanning or other permanent media. This process will be expedited so that the notebook can be returned quickly to the researcher. Upon completion of the scanning process, the laboratory notebook will be returned to the researcher, for use as reference in the laboratory, or put into permanent storage at the researcher's request. One scanned copy will be kept in the library for access at any time. One other copy of the scanned copy will be put into secured storage in a designated location.

B. Hardbound notebook containing electronically captured data

- Even in GR characterization initiatives where a large amount of digital GR data is generated and stored directly in computers or online, a written laboratory notebook, with all of the guidelines referred to above, is still required. In this setting, however, much of the GR data referred to in the laboratory notebooks may exist in electronic files. The laboratory notebooks should contain a summary of the information in those files and also give the name of the file (and format) in which the GR data or other data have been stored.
- The electronic data should be backed up and archived weekly. A new and separate file should be provided as a place to store data. Details of these files and the back-up procedure should be described to all researchers and managers in a memo. These backed-up files should never be opened except for litigation, digital time stamping or matters related to the relevant patent-granting authority.

C. Hardbound notebooks generated by computers

- The same guidelines as for hand-written laboratory notebooks apply to hardbound notebooks generated by computers, sequencers or automated phenotyping installations. The difference is that rather than purchasing a laboratory notebook and writing in it, the research process and results are documented electronically. Where this is practical from the size and scale of files, the documentation should be printed out on a regular basis and then bound to form a laboratory notebook. The printed material should be clearly labelled with the information that will appear on the front of the bound book. Once bound, the laboratory notebook will be assigned a number, recorded, and returned to the researcher or archived, upon request.
- Each experiment or characterization process is to be described and each page should be numbered and signed, countersigned, and dated. Each week these experiments or characterization processes are to be saved in a designated data file as described in a memo. Also, as with hardbound notebooks, data such as sequence listings, graphs, photos of gels, and so on, which can be attached to the laboratory notebook page should be attached using the same methods as described above. The policy on use of mobile phone cameras for such purposes should be discussed and standardized.

B. Sample invention disclosure form

Data fields and information usually included in invention disclosure forms

- **Inventor details**, including employer, affiliation and contact details
- **Invention**, including title, abstract, description, embodiments and potential uses (including, if possible, industrial applications) of the invention
- **Date and place of invention,** particularly ‘conception’ of the invention
  If relevant separately and applicable, date of reduction to practice (may be the date of invention)
- **Research funding sources** with the invention was made, if any
- **Date of public disclosure**
- **References**, including copies of articles and other publications that might be novelty-destroying in the course of patent examination.

C. Sample copyright log

- As described in section V.B.2 (During characterization, Copyright management), it may be useful to maintain a copyright log of the proprietary copyright materials you are using in your work and the publications resulting therefrom. A purely illustrative example of a copyright log may look like this:

Place, Date	Copyright material used	Page # and book # in your lab notebooks	Need for permission or license?	Timing for permission needed	Copyright clearance obtained
			(y/n; if no, why not)	(publication or research stage)	(date, right holder, permission location)

D. WIPO Standard ST.26

WIPO Standard ST.26 can be downloaded at:
https://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01.pdf

[End of Guide]