

for public comments

Strategy Tool for Improved Use of Genetic Resources and Genetic Resources Data as Intellectual Property Assets

**Comments may be sent by email
to grtkf@wipo.int by January 31, 2024**

Version 1, December 13, 2023
Draft for comments

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1 INTRODUCTION

This Annex to the WIPO Intellectual Property (IP) Guide for Genetic Resources (GRs) and Genetic Sequence Data provides a Strategy Tool as part of the WIPO Toolkit for Rights Management in GRs and Data. It aims to provide a simple, short tool for users who are not familiar with IP to guide decision making. It is intended for anyone seeking guidance to develop an IP strategy for GRs and related genetic sequence data.

Disclaimer: WIPO neither endorses nor opposes any particular IP strategy for GRs and GR data. This Tool does **not** provide legal advice nor any policy guidance regarding the exercise of IP rights or other rights relating to GRs, GR data, GR-based innovations, or GR-based products. Nothing herein 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.

2 BASIC CONSIDERATIONS FOR AN IP STRATEGY

While creating prior art by making material and data publicly available is also an IP strategy as it protects freedom-to-operate, usually any obligations¹ which an innovation owner wants to impose on 3rd parties requires first establishing a right. Only exceptionally IP rights are established without any activity of the owner: Copyright is established by the act of creation but is usually not applicable to GRs and GR data. The most suitable IP right will depend on (1) statutory requirements and limitations, (2) the maturity of the GR innovation, and (3) the value and lifecycle of the innovation.

2.1 STATUTORY REQUIREMENTS

Many countries exclude GRs and their parts (including sequences) *as such* from patentability as “products of nature”, which limits patents to man-made innovations based on these GRs (e.g., GM traits). Other countries exclude plants and animals and essentially biological processes for their production from patentability and refer related innovation to *sui generis* systems like plant breeder’s rights (PBRs). However, despite these limitations many GR innovations are still patentable:

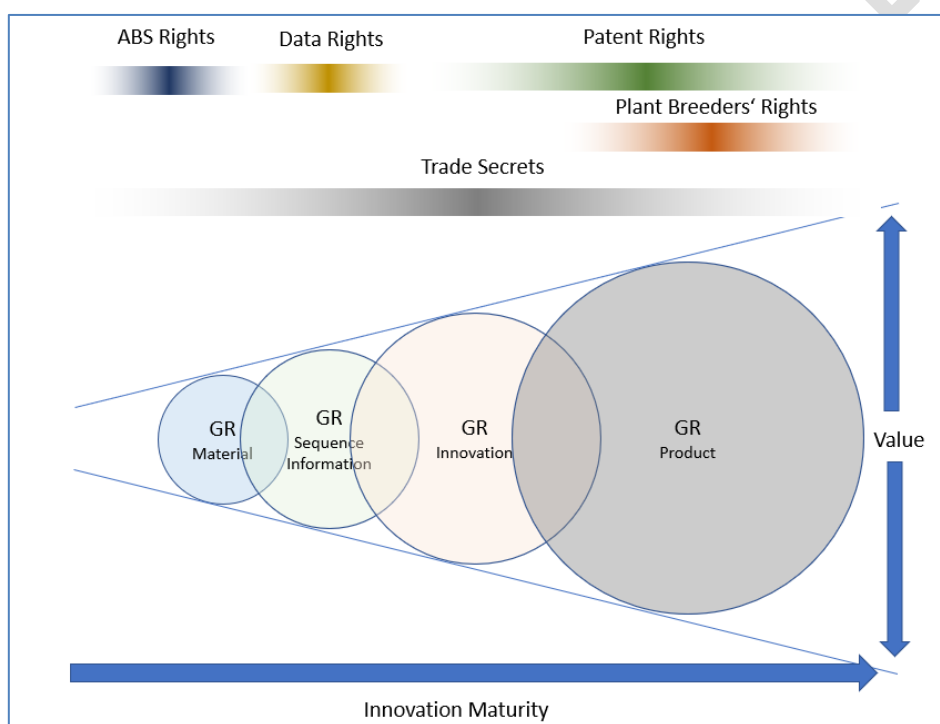
- A new naturally occurring gene sequence for a plant disease resistance gene could be patentable as part of a transgenic expression construct. Plants comprising such construct can be directly protected by patent claims in some countries, and indirectly through a claim on the construct in others.
- Sequences for a new naturally occurring virus can be protected for example in a method for creating a vaccine or as markers for diagnostic kits.

¹ Obligations could include monetary compensation but also no filing of patents or grant backs in case patents are filed.

2.2 MATURITY OF THE GR INNOVATION

Maturity in this context means essentially how much the GR material or related data has been developed, investigated, characterized, or researched. For example, a GR could be in a raw state, that is, essentially just the mere physical existence of the GR material, or raw data obtained from a sequencing project. Or a GR could have been characterized with respect to its unique characteristics, which could enable new innovations.² With maturity, usually also the value of the asset increases. The more advanced an innovation is, the more IP tools are available, also in combination. The following graphic illustrates the relationship:

Figure 1: Relationship of GR related assets with value and rights³



The most common “registered IP rights” which apply to GR innovations are patents and plant breeders’ rights. “Unregistered IP rights” primarily include trade secrets. Also, the rights established under respective biodiversity legislations are – in principle – rights that can be licensed.

The requirements, costs, and scope of rights of the different IP rights relevant for GR innovations can differ substantially. The following must be considered:

² The mere possession of a GR or related data is rather a discovery, which is less suitable for protection by registered IP rights. Once the GR innovation has been further developed so that it – for example – solves a technical problem, registered IP rights are possible.

³ Definitions: Global biodiversity is protected by the Convention on Biological Diversity (the CBD). The CBD provides that the benefits arising from the use of genetic resources should be shared with the country providing these resources. This is the concept of “access and benefit sharing”, or ABS. Data Rights refer to rights in “technical data” and “computer software”. The basis for the right could be know-how/trade secret, regulatory data protection (e.g., data exclusivity) or rights associated with biodiversity (e.g., digital sequence information (DSI)). Patent Rights refer to the rights resulting from a patent application or patent either by ownership or license. Plant Breeders’ Rights (PBRs) refer to the rights to a new plant variety as – for example – granted under the UPOV convention. Trade secrets refer to information of value to a business or market that is not generally known to others in the business or market.

Requirements & Costs:

- **Patents:** The prerequisites for patent protection are high and require inventiveness / non-obviousness, with the consequence that the allowance rate for GR innovation is usually not higher than 50%. The costs for patent protection (including attorney fees) for a GR innovation can easily attain USD 100,000.
- **Plant Breeders' Rights:** The hurdle for plant breeder's rights is lower than for patents. The breeder needs to show distinctness, uniformity, and stability (DUS) and the allowance rate is usually higher than 95%. Also, the costs are more moderate and rarely exceed USD 10,000.
- **Trade secrets** require that adequate means for protection have been taken. While there are "office fees" associated with trade secrets, the costs (monetary and non-monetary) for security measures can be substantial.

Use exemptions: Under plant breeders' rights, farmers in most countries enjoy a right to use farm-saved-seed,⁴ in some countries against a fair compensation of the IP owner. In contrast, there is usually no farm-saved-seed exemption for plants protected by patents.⁵ Also in the field of healthcare, physicians and pharmacists in many countries enjoy certain privileges under patent rights.

Enforcement of rights: Other challenges result from the fact that many GR-based products – like seed – can be propagated. While in many countries the propagation of patent protected living material should be considered "making" of a protected product, in others the sale of the original material may render the related IP rights exhausted. This has not only implications on the respective license agreement, but it may also require agreements between the licensee and downstream users (e.g., farmers). Grower agreements, bag tags and other legal elements may be necessary to protect the interests of the IP right holder.

GR-related due diligence obligations during the IP filing process: The patent offices in many countries and the Plant Breeders' Rights offices in some countries require a declaration of source and origin if an invention or new plant variety has been made by using a GR. Lack of submitting this information may result in a rejection of the patent. A false declaration may render the patent invalid. Therefore, the obligation to meet these due diligence obligations and to provide the required information needs to be clearly regulated in a technology transfer agreement.

2.3 VALUE AND LIFECYCLE OF THE GR INNOVATION

Implementing IP strategies can be expensive, and measures should be proportionate, considering where, by whom, to which extent, and how long your invention will likely be used. As a rule of thumb in a GR-related industry, out of the potential maximum profits generated by an innovation, not more than 5% should be used for acquiring or establishing an IP right.

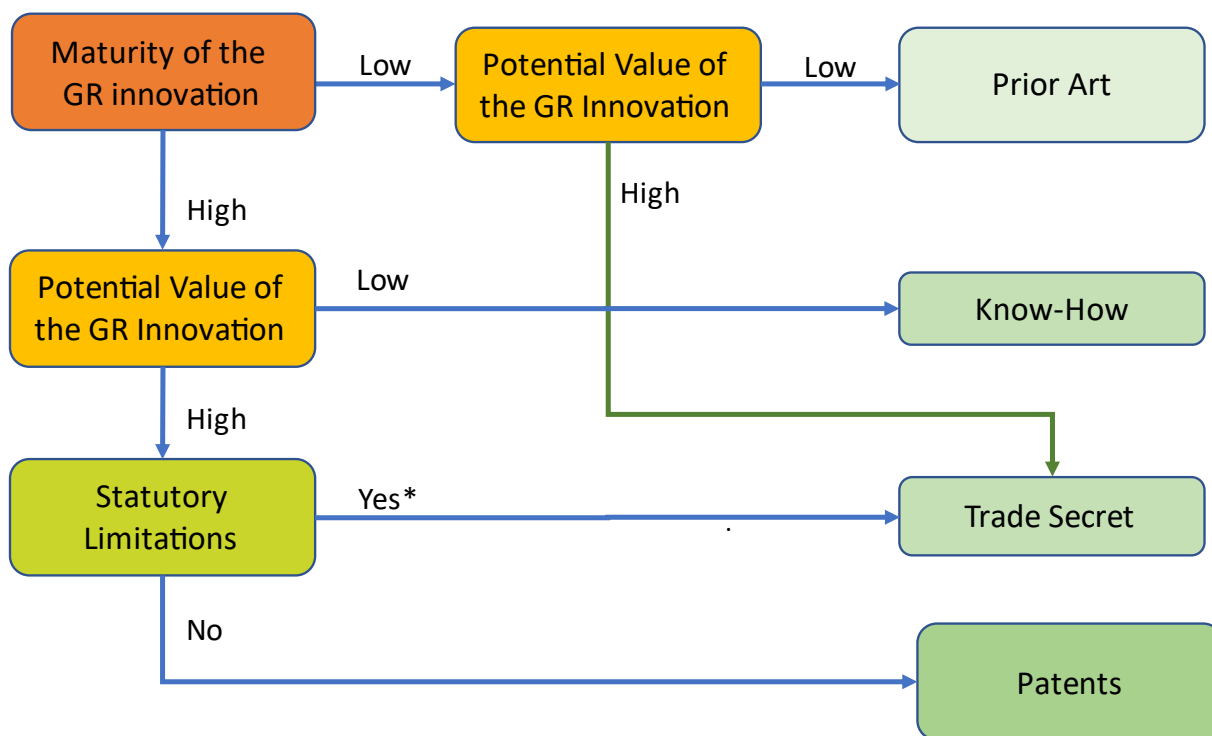
To obtain registered IP rights can take substantial time. Patents for GR innovations usually may require five or more years from first filing to grant. Plant breeders' rights usually require two/three seasons of DUS trails. Such efforts are usually only justifiable if the expected lifecycle of an innovation is at least 10 years. If the innovation lifecycle is rather short, know-how protection and trade secrets might be the more effective way of protection.

4 Farm-saved-seed means the use of harvested material (grain) and seed in a subsequent season. It is a common practice in certain field crops like wheat, soy, and potatoes.

5 An exception is the European Union, which has incorporated a farm-saved-seed exemption also into patent law.

Registered IP rights (except for copyright) are usually not global but rather territorial and established on a country-by-country basis. Since it is very expensive to obtain registered IP rights in all countries, part of an IP strategy is to select those countries that will provide the greatest return on the investment. Usually these are the countries where (1) the protected products have their largest market and (2) potential competitors have major development and production capacities.

Figure 2: Decision tree for choice of IP tool



* In case of statutory limitation for **plant life science innovations**, plant breeders' rights can be considered as an alternative.

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