Genetic Resources and Genetic Resources Data Licensing Tool

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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 Licensing Tool for GRs and Data as part of the WIPO Toolkit for Rights Management in GRs and GR Data (the Toolkit). Its aim is to provide a simple and accessible starting point for users who are not familiar with the IP issues that arise during licensing or transfer of knowledge and technology related to GRs and GR data. Its purpose is to compress the full complexity of IP issues arising during licensing into a simple, short, and accessible checklist for decision making by stakeholders, including licensors and licensees. It is intended for anyone providing or receiving intangible assets related to GRs in the context of knowledge and technology transfer.

1.1 PURPOSE

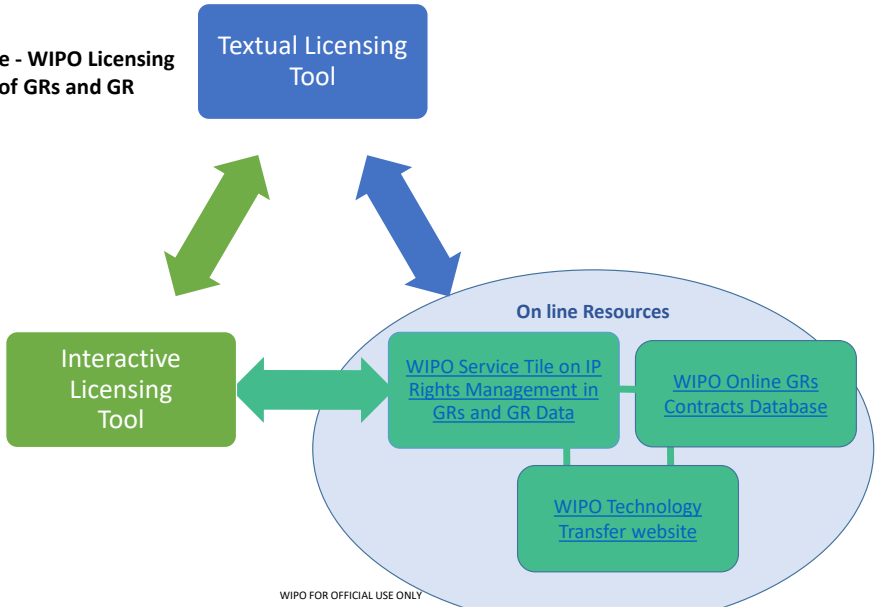
This Tool aims to provide practical guidance for licensees and licensors who wish to license IP rights for genetic material and/or genetic data. The guidance refers to, but does not address, related legal frameworks, in particular, access and benefit-sharing (ABS) frameworks applicable to GRs involved in the characterization and innovation process.

The objective of the Tool is to give you a process framework and complementary information resources for licensing of GRs and/or GR data, without giving legal advice on the specifics of any individual licenses. It is essential to obtain specialized, professional legal advice from other sources and to recognize that this Tool does ***not*** provide such advice.

Target audiences: This Tool aims to serve licensors and licensees who are involved in the licensing of GRs and/or GR data. This may include providers, intermediaries and recipients of GRs and/or GR data. The potential target audience may include the entire range of licensors and licensees, including academic institutions, private sector companies, public research institutions, or other innovators and GR stakeholders wishing to license GRs or GR data.

Structure: The Tool is structured in three complementary components which provide different levels, types and amounts of practical information on licensing of GRs and GR data. The three complementary components – the Textual Licensing Tool, the Interactive Licensing Tool and the Online Licensing Resources - are connected via hyperlinks, and you can navigate seamlessly between them to different levels of detail if you have an Internet connection.

Figure 1: Structure - WIPO Licensing Tool for Licensing of GRs and GR Data



You are currently reading the “Textual Licensing Tool”-component of the Toolkit.

1.2 DISCLAIMERS

WIPO neither endorses nor opposes any particular policy or approach to IP rights and IP rights management in licensing of GRs and GR data. This Guide does ***not*** provide:

- Legal advice on licensing of IP rights or any other rights relating to GRs, GR data or information, GR-based innovations, or GR-based products. References to information sources, where such advice or related information are available, are included in the relevant WIPO online resources;
- any policy guidance regarding the exercise of IP rights or other rights relating to GRs, GR data or information, GR-based innovations or GR-based products;
- 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, and additional references to information sources are in the relevant chapters and text boxes;
- any legal status information, including licensing information, on individual GRs, GR data or information, or GR-based innovations or products.

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 GRs, subject to national legislation.

1.3 DEFINITIONS

For the purposes of this Tool,

- **“license”** means a grant by the holder of a right (for example, an intellectual property right like a patent, a copyright, or the right to proprietary technology protected by secrecy) to another to use or exploit said right but not to own such right;
- **“license agreement”** means a legally enforceable contract or other transaction that defines a license grant;
- **“licensee”** means the business, organization, or individual that has been granted a license;
- **“licensor”** means the business, organization, or individual that owns or legally possesses a right and grants a license to that right. Usually, the licensor is either the right holder or the holder of a license with the right to grant sublicenses, usually in case of exclusive licenses.

For specific examples also see the template agreements and sample agreements.

2. GENETIC RESOURCES: LICENSING AND UTILIZATION SCENARIOS

While in practice the licensing scenarios related to GRs are highly diverse, they can – in principle – be grouped into a limited number of scenarios which largely depend on two primary factors:

(i) **The quality and value of the "asset" related to the GR:** Quality in this context means essentially how much the GR has been further developed, investigated, characterized, or researched. For example, a GR could be in a very raw state, that is, essentially just the mere physical existence of the GR material. Or a GR could have been characterized with respect to its unique characteristics, which would already enable new innovations. With increasing quality usually also the value of the asset increases.

(ii) **The "objective" of the Licensor[1] possessing the GR:** The stakeholder governing the GR may have different intents and interests. Some simply want to make sure that the GR remains unencumbered from intellectual property rights and available for free to all under a proper governance. Others may want to use a GR as a basis for a cooperation to create new innovations which benefit specific stakeholders, such as – for example – a commercial partner in a private-public partnership or users in the country of origin.

Table 1: Licensing and utilization scenarios for GRs.

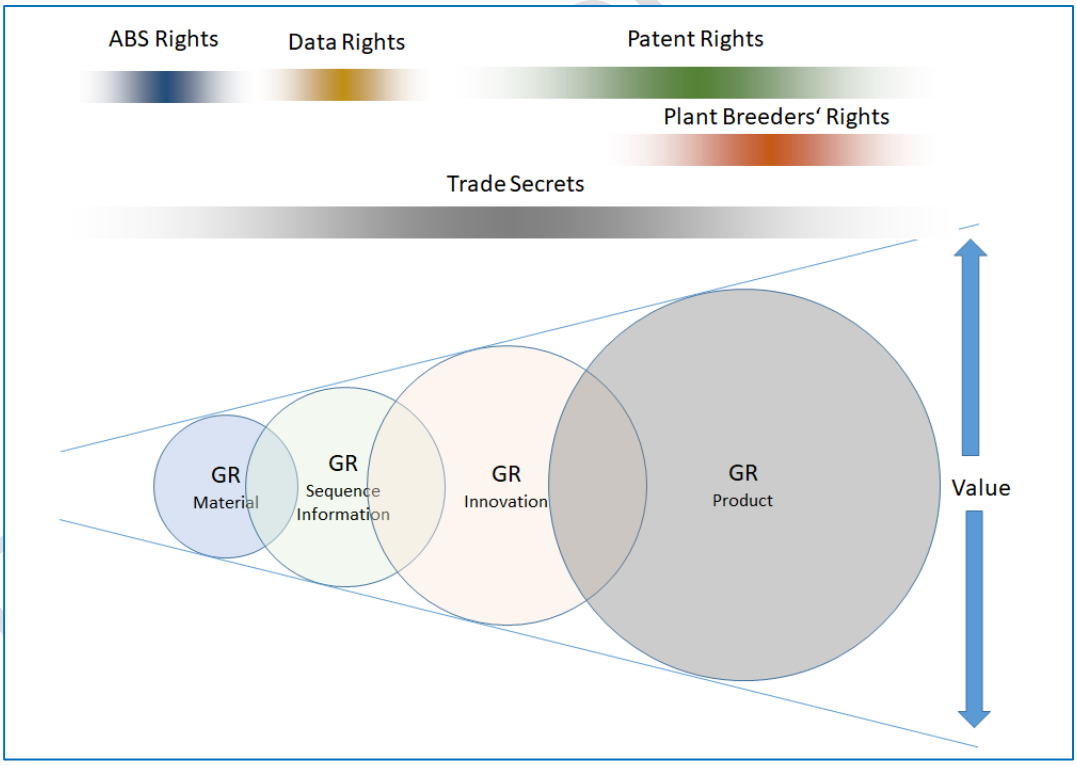
		Your IP Asset → IP & Value increases			
		GR Material	**GR Information (Sequence Data)**	**GR Innovation**	**GR-derived Products**
Your Objective → Commitment Increases	**Ensure FTO** (Free access for all)	• **IP Strategy:** Open access • **Tech Transfer Approach:** Material Transfer Agreement (MTA), Confidentiality Agreement (CDA) 3.3		• **IP Strategy:** Prior art creation • **Approach:** Prior use, sale, publication 3.5	
	Out-licensing technology transfer (including access & benefit-sharing)	• **IP Strategy:** Trade secret • **Tech Transfer Approach:** Trade Secret License Agreement 3.4		• **IP Strategy:** Patent / Plant Breeders' Right (PBR) • **Tech Transfer Approach:** (i) IP License Agreement 3.1 (ii) Patent Pool & Clearing House 3.2	
	Collaboration (Partnership)	• **IP Strategy:** Trade secret • **Tech Transfer Approach:** Collaboration Agreement 3.6		• **IP Strategy:** Patent / Plant Breeders' Right (PBR) • **Tech Transfer Approach:** License & collaboration Agreement 3.6	

[1] Licensor in this context means the legal or natural person who has the right to transfer the GR or the related information and innovation.

Both the quality and value of the asset and the different objectives influence the suitable licensing scenarios. When the combinations of assets and objectives are mapped into a coherent decision-making matrix, they result into five primary GR licensing and utilization scenarios, which are mapped in the decision-making matrix (see Table 1). The five primary GR licensing and utilization scenarios are subsequently elaborated in the six sections of chapter 3 (sections 3.1 to 3.6 below).

It should be noted that – in general – the value increases from mere GR material over sequences to innovations to finished products. In addition, the next level of IP and asset value often incorporates the earlier ones: for example, a GR-related innovation is usually based on and incorporates GR-derived sequence information. The more advanced an innovation is, the more elements of IP licensing and technology transfer - that is, transfer of rights in intangibles and of tangible materials - are combined. In consequence, agreements may comprise elements of IP licenses, confidential disclosure agreements (CDAs), and material transfer agreements (MTA). The following graphic illustrates the relationship in a different way:

Figure 2: Relationship of GR related assets with value and rights[2]



[2] Definitions: Global biodiversity is protected by the Convention on Biological Diversity (the CBD). The CBD recognizes that countries have sovereign rights over GRs on their territory and encourages them to ease access to these resources "for environmentally sound uses". It also provides that the benefits arising from the use of GRs 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 (for example, data exclusivity) or rights associated with biodiversity (for example, 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.

What makes GR related IP strategies and technology transfer agreements special?

While many elements of a GR-related IP and technology transfer strategy follow the general approaches, some considerations and elements are special due to the nature and the legal framework for GRs. The following must be considered:

- **Scope of patentability:** Many countries exclude GRs and their parts (including sequences) from patentability as "products of nature", which limits patents to man-made innovations based on these GRs (for example, genetically modified (GM) traits). Other countries exclude plants and animals from patentability and refer related innovation to *sui generis* systems like plant breeders' rights (PBRs).

- **Use exemptions**: In the fields of agriculture and healthcare, both farmers and physicians in many countries enjoy certain privileges under patent and PBRs. For example, farmers may have a right to use farm-saved-seed[3] against a fair compensation of the IP right owner. Here, it needs to be regulated in the respective technology transfer agreement how the rights of the IP right owner are enforced and how the farm-saved-seed royalties are collected and shared between the owner of the IP right and a licensee.

- **Scope of rights:** GR-related technology transfer agreements are almost always related to more than one IP right. While they usually grant rights under a registered IP right, like a patent or plant breeders' rights, they usually govern the transfer of proprietary material and/or know-how, and confidential information. This "mixed character" has implications on the term of the agreement (as rights to know-how and proprietary material have no pre-defined expiration date). It may also impact payments structure as usually the value of the different assets needs to be reflected.[4]

- **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 (for example, 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 innovation process**: Many GRs will be covered by the legislative framework for biological diversity, and requirements for prior informed consent (PIC) and ABS may apply. As a lack of compliance may have severe consequences for bringing to market the resulting products, a technology transfer agreement needs to clearly regulate the responsibilities of the parties. Usually, the licensor will be the party which has accessed the original GR and is directly bound by the compliance and ABS obligations. A licensee should have a strong interest in a clear representation and warranty that the licensed GR-derived material was developed in compliance with the applicable biodiversity legislations. Based on the respective country of origin, copies of permits and agreements should be provided.

[3] 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.

[4] For example, the value of a license (and the related payments) is usually reduced once the registered patent rights expire (or are revoked) and only the rights to proprietary material and information remain in place.

Likewise, a licensor should pay attention to meet the requirements of the ABS agreements, which may require him/her to impose certain provision on the licensee. For example, many countries require a due diligence declaration once a GR-derived product is launched into the market. Usually, the licensee will have to make this declaration, but will only be able to do so if he/she received the necessary information from the licensor.

- **GR-related due diligence obligations during the IP filing process:** The patent offices in many countries and the PBRs offices in some countries require a declaration of source or 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 in some countries. A false declaration may render the patent invalid. Therefore, the obligation to meet these due diligence obligations and to provide the required information need to be clearly regulated in a technology transfer agreement.

3. SOLUTIONS FOR LICENSING AND UTILIZATION OF GENETIC RESOURCES

In practice, technology and IP transfer strategies and approaches are unlimited and determined by the parties' interests. In consequence, the following solutions are merely "role models," that is, typical solutions which have been successfully tested in practice. Alternative models and/or combinations of the solutions described below are also feasible. The following sections will describe critical elements, limitations, and potential problems of the respective solutions. Examples, model agreements and model clauses are provided. This tool should not be considered "legal advice". In case of doubt, the support of attorneys and/or technology transfer experts is advisable.

3.1 PATENT AND PLANT BREEDERS' RIGHTS LICENSING STRATEGIES FOR GR INNOVATIONS AND PRODUCTS

This section is applicable if a GR has already been researched and/or developed and registered IP rights – for example a patent or PBR, or at least an application therefore – has been obtained. Even more valuable would be a situation where such IP rights can be provided together with a product or the prototype of a product, such as – for example – an optimized plant variety, or the lead structure for a new drug or crop protection active ingredient. In such a case, the GR-based product and related IP rights can be licensed to a licensee for further development and subsequent commercialization.

The following elements should be considered in the context of such a scenario:

(i) **Primary Intent:** This scenario addresses how to manage licensing of GR-related innovations or products in a sustainable[5] and mutually beneficial[6] way.

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[5] "Sustainable" in the context of a license means that the contractual relationship and the related sharing of benefits arising from the licensing of the relevant rights (including license income) can be maintained at a certain rate or level over an extended period of time. This requires that the licensed asset (for example, technology, data) is differentiated (that is, not a me-too solution) and retains value over a longer period of time, and that the license is supported by rights, which ensure exclusivity, that is, the right to exclude others from using the asset without a license. Usually, these are IP rights like patents, plant breeders' rights, or trade secrets. Without differentiating value and protection by exclusive rights, a license agreement is unlikely to be sustainable.

[6] "Mutually beneficial" in the context of a license means that the added value resulting from the use of the licensed asset is shared between licensor and licensee. As a rule of thumb between half and two thirds of the added value is retained by the licensee, and between one third to half of the value is transferred by the licensee to the licensor, usually in form of the payment of a licensee fee. Mutually beneficial licensing can also include cross-licensing, that is, the owner of one technology receives access to another technology in lieu of the granted

(ii) Critical Questions and Considerations: Several questions need to be addressed prior to any engagement with third parties.

The first set of questions relates to your IP Strategy:

What makes an effective IP strategy? An IP strategy is a plan – consistent with a person's or entity's objectives – to acquire IP assets and leverage the most value from existing IP assets. The acquisition of IP assets can happen through one's own Research and Development (R&D) activities, or from third parties (for example, through in-licensing). Leveraging IP assets can happen through maintaining exclusivity and thereby a competitive advantage (for example, higher prices), through creating income from licensing, or through contributing IP assets in a research or commercial development collaboration. Thus, to design a fit-for-purpose IP strategy, the following should be considered:

- **What is your objective (see Table 1)?** (i) Do you want to maximize freedom-to-operate, that is, enable the broadest possible use of your innovation by the public and minimize any third-party encumbrances? Or (ii) Do you want to maximize an ABS approach, that is, broad out-licensing to third parties for royalties or alternative benefits? Or (iii) Do you want to find collaborators to enable rapid development of your innovation into a commercial product? Or (iv) Do you want to maximize your exclusive position?

  Depending on your intent, different IP assets can be used. For objective (i), often a simple legally certain publication to create a technical public disclosure is sufficient. For objectives (ii) to (iv), the targeted use of IP assets to establish licensable rights and/or rights to exclude unauthorized parties is essential.

- **What is the value, territorial use, and potential lifecycle of your innovation?** Implementing IP strategies can be expensive, and measures should be proportionate, taking into account 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.

- **What are the available IP assets?** Depending on the nature and maturity of your innovation, different IP assets are available. For example, mere GR-derived sequence information usually cannot be patented, either because they lack a specific, substantial, and credible utility or are considered "products of nature." However, such sequence information can be kept as trade secret. Once a specific sequence has been shown to solve a specific problem (for example, confer a resistance against a disease), filing a patent application becomes possible. If the sequence is incorporated into a product, such as a plant variety, applications for PBRs and, in some countries, patents can be filed.

license, or a collaboration in which both parties contribute their respective technologies to a joint research or development project to benefit both parties.

- **What rights do you have already that can be licensed in a sustainable way?** Licensing – by definition – requires that there are rights which can be licensed: **No right – no license**. Such rights could be "registered IP rights" such as patents, PBRs, or copyright[7], but also "unregistered IP rights" like trade secrets (see Chapter 3.4). Also, the rights established under respective biodiversity legislations are – in principle – rights that can be licensed.

  Trade secrets, that are information of value not generally known, are difficult to manage and to license.[8] While trade secrets have no borders and can form the basis for worldwide licensing, they do not provide a sustainable basis for a license if the trade secret is eventually disclosed, for example, by the sale of a product (for a discussion of trade secret licenses, see Chapter 3.4). In consequence, the best foundation for a robust, sustainable license are registered IP rights, especially patents or PBRs.

  Registered IP rights (with the exception of 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 is all countries, part of an IP strategy is selecting those countries that will provide the greatest return on the investment. Usually these are the countries where (i) the protected products have their largest market and (ii) potential competitors have major development and production capacities.

- **What rights can you still obtain that can be licensed?** If there are no IP rights yet which could be licensed, it is usually critical to register these rights prior to any engagement with third parties. Otherwise, any disclosure to such third party might be considered "novelty destroying" and an absolute bar to establish the right. It needs to be carefully assessed what rights are possible to obtain. This will usually depend on the extent of investigation and innovation on the GR. It may also depend on statutory limitations, especially to patentability, in some countries.

The second set of questions relates to the kind of licensing agreement you may want to enter into:

- **What kind of license do you want to grant?** Licenses can be exclusive or non-exclusive; they can be granted under bilaterally negotiated license agreements or under an open licensing framework with standard license agreements (see also under Chapter 3.2).[9] An upfront licensing policy decision is often meaningful. For example: While for pharmaceuticals and other regulated technologies an – at least temporary – exclusive license is often indispensable to justify the high investments, for other technologies a non-exclusive license often ensures better technology dissemination and higher benefit-sharing. In non-exclusive licenses, the licensee receives freedom to operate under the licensor's IP assets in exchange for some

[7] Generally, copyright protects original, tangible works of authorship, for example, books, paintings, computer programs. Copyright in such works comes into being upon their creation. Copyright registration is possible, but optional.

[8] You may find more information on trade secret law, policy and practice at this WIPO webpage.

[9] In some industries, competitors agree to establish technical standards for products and patents on such standards are often pooled and licensed under a standard agreement. See also Chapter 3.2, for a discussion of The International Licensing Platform – Vegetables (ILP) and pooling of vaccine patents, both of which license under standard agreements.

form of benefit, usually royalties. In exclusive licenses, the licensee in addition usually receives the right to enforce the related IP rights against infringers.

Licensees often require exclusive licenses, that is, to be the only party which is entitled to make use of the licensed GR or innovation in the licensee's geographic or product market. Such exclusive licenses have the risk of underutilization, that is, the licensee not being willing or able to satisfy market needs and/or make full use of the potential of the GR or innovation. Also, in view of the general consideration that GRs should usually remain accessible for all interested parties, an exclusive license in a critical, large market should be an exception. Such exception can be justified if the related product requires a highly expensive and risky market authorization process as it is required for pharmaceuticals, crop protection compounds, or GM traits.

If an exclusive license is considered, it should be accompanied with (i) clauses for due diligence requirements (that is, obligations to reach certain utilization milestones and timelines) and/or (ii) clauses that establish minimum obligations for sharing the benefits arising from the use of the licensed rights (for example, minimum annual payments). A breach of such obligations should result either in a termination of the license for cause or a conversion to a non-exclusive license.

- **What rights do you want to transfer? What limitations should apply?** An IP rights license may be broad (for example, worldwide, for all rights, for the life of the IP) or more refined and restrictive. If your strategy is to maximize worldwide commercialization or benefit-sharing, granting restrictive licenses to several licensees may be appropriate. No single licensee with worldwide rights will invest evenly in all available markets. Several non-competing licensees with exclusive rights in limited product or territorial markets are more likely to maximize distribution and benefit-sharing. Such restrictive license agreements will require a clear specification of the rights granted, especially for (i) the field of use, and (ii) the territory. A field of use license confines the licensee to a particular embodiment of a product (for example, COVID vaccine specific to Omicron variant) or to a particular market (for example, sales in bulk to hospitals as opposed to retail sales to pharmacies). A territorial restriction limits the licensee to manufacture and sell in particular geographic areas (for example, the EU, Asia).[10] An IP licensor may employ its licensees to further license the IP assets through (iii) sublicensing rights. The right of a licensee to grant further license rights to sub-licensees depends on a specific grant by the licensor. For some GR-related innovations (for example, seeds-related), sublicensing is a necessity, for others, it could undermine proper governance and could cause a loss of control. Sublicensing can also be restricted, that is, just to make and use the product designed by the original licensee (restricted sublicenses), but not to make independent products (so-called "naked" sublicenses).

- **What obligations for the licensee should apply?** In addition to due diligence obligations to make a certain use of the licensed GR and innovation, licensees usually have obligations for (i) monetary benefit-sharing (milestone payment and/or royalties on net sales), (ii) non-monetary benefit-sharing (for example, grant-back licenses to improvements or non-profit dissemination for smallholder farmers or in low- and middle-income countries), (iii) reporting on use and/or (iv) reporting third party infringement, etc.

[10] While a license may be restricted to a geographic area, for example, Asia, such a restriction may only be enforceable in countries where the licensor has patent rights. As discussed below, a trade secret license may be enforced as a contract regardless of national boundaries.

- **What risks need to be managed?** The licensor will usually limit risks which arise from a licensee's use of the GRs and innovation. Associated risks should be managed with clauses disclaiming or regulating liability and/or clauses imposing indemnification obligations on one or both parties.

  In addition, clauses that address the risk that the licensee breaches the agreement or becomes insolvent are needed. Usually, such risks are managed with clauses providing a right for the licensor to terminate the agreement for breach. In some jurisdictions, termination of agreements due to bankruptcy is not possible, as the agreements are considered assets of the debtor, so agreements with parties in such jurisdictions must be carefully drafted to provide the greatest flexibility in the event of bankruptcy.

(iii) Examples and Template Agreement:

- A sample contract which relates to GR sequences can be found here: https://www.wipo.int/tk/en/databases/contracts/texts/ricedata.html

3.2 COLLECTIVE LICENSING: PATENT POOLS AND PATENT CLEARING HOUSES

For the licensing of GR-related assets, "exclusivity" is often not desirable. To enable collaboration and/or broad dissemination of GR assets and related innovations, different models of collective licensing have been developed. A robust collective licensing framework can be established if it is concurrent with the license of related registered IP rights like patents. Any breach of the contract can be sanctioned by a termination of the license. If the IP right is robust and the underlying invention valuable, such sanction is usually sufficient to establish a sustainable collaborative licensing framework with a sufficient pull-in effect[11]. In principle, the solutions can be grouped in four models:

(a) **"Patent pools"** deal with complex innovations on which multiple owners have patents that block market entry. A pool creates a "one stop shop" which enables collective licensing for a reasonable price. They "clear" patent thickets with pro-competitive effects. They usually do not allow to in-license individual patents comprised in the pool but only the entire bundle of patents. Patent pools also require careful anti-trust consideration and usually regulatory clearance.

(b) **"Patent clearing houses"** facilitate access to collections of patented technologies. They usually work with standard agreements. Clearing houses are therefore less an approach to manage patent tickets than to pragmatically establish FRAND terms[12]. The international Licensing Platform – Vegetables (ILP) (see below) is an example for a clearing house. [13]

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[11] An open access framework has maximal impact if the joining parties make also their own related IP assets available under reciprocal terms. This is especially important for IP assets that cover improvements to the foundational IP. If such improved IP is not made available, the freedom-to-operate and with this the value of the framework will shrink over time. However, parties would only accept making their own IP assets available if (i) the foundational IP is sufficiently strong, (ii) the covered innovation is sufficiently attractive and (iii) all joining parties must share their IP on reciprocal terms. This creates a "pull-in effect".

[12] FRAND, fair, reasonable, and non-discriminatory terms, denote a voluntary licensing commitment that standards organizations often request from the owner of an intellectual property right (usually a patent) that is, or may become, essential to practice a technical standard. Available at: https://en.wikipedia.org/wiki/Reasonable_and_non-discriminatory_licensing.

[13] An interesting overview and assessment of numerous collaborative licensing models in the genetics space can be found in *Gene Patents and Collaborative Licensing Models. Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, Edited by G. van Overwalle, Cambridge: Cambridge University Press (2009).

(c) **"Licensing Pledges"** are declarations to grant licenses, which can be made in various forms, for example by declarations at the patent offices. Some seed companies have made "licensing pledges" through e-licensing and other instruments. [14]

(d) **"Open Source Models"** [15] have been primarily developed for software related innovations where copyright is established automatically without the need for any registration. There have been attempts to establish open source models for plant related innovations by obligations not to patent. For example, the Open Source Seed Initiative (OSSI) was established in 2014 with a "pledge to preserve unencumbered exchange of germplasm for breeding and research purposes" with rights to save and replant harvested seed from OSSI varieties.[16]

(iii) Examples and Template Agreement:

- http://www.iphandbook.org/handbook/resources/Agreements/links/5-1 Health Tech Mutual NonAssert 2 CAMBIA BiOS.pdfThe International Licensing Platform – Vegetables creates a framework for an open licensing of vegetable related inventions and GRs (see also case study under (iv)). The associated standard license agreement can be found here: https://www.ilp-vegetable.org/uploads/Bestanden/ILP%20Founding%20Docs/SLA%20Annex%201%20-%20April%202018.pdf

(iv) Case Study: International Licensing Platform – Vegetables (ILP):

The International Licensing Platform – Vegetables (ILP) is a widely accepted "patent clearinghouse" in plant breeding.[17] It was founded in 2014 with support from the Dutch government and currently represents more than 60% of the global vegetable seed market.[18] Any party can join the ILP irrespective of whether it owns patents or not. The ILP enables access to patented traits under fair and independently determined financial conditions.[19] While research and breeding is free, the licensee must pay a royalty for the commercialization if and where the seeds are covered by the patent. In addition, the ILP provides access to "variety patents" which in the US protect specific plant varieties.[20] In summary, the ILP is based on the following key elements:

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14 *Syngenta TraitAbility - e-Access to Crop Licensing*. Available at: https://www.traitability.com/.

15 Kloppenburg assesses various Open Source models in detail. Kloppenburg J (2010) *Impeding dispossession, enabling repossession: Biological open source and the recovery of seed sovereignty*. J. Ag. Change 10:367–388. Available under: file:///C:/Users/micha/Downloads/Impeding_Dispossession_Enabling_Repossession_Biolo.pdf. Accessed dec. 30, 2020.

16 Luby CH and IL Goldman (2016a) *Freeing crop genetics through the open source seed initiative*. PLoS Biol. 14(4):e1002441. doi: 10.1371/journal. pbio.1002441.

17 OECD (2018) *Concentration in Seed Markets: Potential Effects and Policy Responses*, OECD Publishing, Paris. doi: 10.1787/9789264308367-en. Available at: https://www.oecd-ilibrary.org/agriculture-and-food/concentration-in-seed-markets_9789264308367-en and https://seedinnovation.ca/wp-content/uploads/2019/01/OECD-Concentation-in-Seed-Markets.pdf. p.197.

18 Detailed information about the statutes, members, and current patent estate can be derived from the ILP webpage: http://www.ILP-vegetable.org.

19 Kock M and F ten Have (2016). The 'International Licensing Platform –Vegetables: A prototype of a patent clearing house in the life science industry. Journal of Intellectual Property Law & Practice 11(7):496-515. doi:10.1093/jiplp/jpw073. Available under: https://www.ilp-vegetable.org/uploads/Bestanden/News/Article%20ILP%20Journal%20of%20Intellectual%20Property%20Law%20&%20Practice%202016.pdf. Kock M (2015) Plant breeding innovations: Free access but not access for free - A new approach to facilitate FRAND licenses for plant related patents. Bio-Science Law Review 14(4):123-129; Bruins M (2015) "A Full Count for Vegetables", European Seed, Vol. 2/1 Available at: https://european-seed.com/2015/04/a-full-count-for-vegetables/.

20 For variety patents, the ILP establishes a cost-free mutual non-assert for breeding of new varieties. This comes as close as possible to a full breeder's exemption under Plant Variety Protection (PVP).

- **Defined Scope**: The ILP provides access to "trait patents"[21] and "variety patents" and enables the use of patented, legally available vegetable material for further breeding. The ILP does not enable use of proprietary technologies nor does it mandate material transfer.[22] The ILP is limited to traits that are not regulated as genetically modified organisms (GMOs).[23] When it comes to new breeding techniques (NBTs), such as genome editing, and the current "patch-work" of regulatory classification, the ILP enables licenses to NBT-derived traits in and for countries where those traits are not considered GMOs. Such limitation is necessary as GMO liability requires a qualification from licensees which would undermine the ILP principle that access is available for everybody.

- **"All-in" and "Pull-in"**: The ILP became the "one-stop-shop" for vegetable trait patents by establishing an "all in" obligation: If a party wants to take a license through the ILP, it has to become a member and make all its own patents relating to vegetables traits and varieties available through the ILP. This "conditional openness" creates a strong pull-in effect. In consequence, the ILP makes available more than 270 trait patent families and numerous variety patents.[24] This represents more than 60% of the relevant patent families worldwide in this field.

- **Contractual Breeders Exemption**: ILP members grant each other a mutual, royalty-free non-assert under US variety patents to use legally available varieties for the breeding and commercialization of new varieties. Two conditions apply: The new variety has to be sufficiently distinct from the original variety, and a notification has to be sent to the patentee.

- **FRAND Terms**: Licensees must pay a royalty for the commercialization of the new variety if and where it is still covered by a patent. The ILP members agree to enter good faith negotiations for a bilateral license. Only if these negotiations fail after three months, the ILP's baseball arbitration[25] mechanism kicks in as a "safety net."[26] The baseball arbitration is based on a standard license agreement ("SLA") where the only negotiable term is the percentage for the royalty on net sales.[27] The parties submit a written proposal for a royalty with supporting evidence. If this does not resolve the dispute, the case goes to the Expert Committee. The experts can only pick the one submission they believe is "more fair". No detailed reasoning needs to be provided.

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21 Trait patents relate to new characteristics such as disease resistance, improved shelf-life, and nutritional value. With respect to trait patents, the ILP is limited to unregulated traits in vegetables, that is, traits which are not considered GMO.

22 However, such rights could be granted under a bilateral license agreement between the members.

23 Handling GM technologies requires specific capabilities which are not compatible with the ILP's requirement to be open for all interest parties. Especially smaller breeders will not have the capability to handle GM technologies nor the capacity to cover for the related risks and liabilities.

24 ILP Patent Register available under: https://www.ilp-vegetable.org/uploads/Bestanden/Patent%20Register/ILP%20Patent%20Register%20-%20total%2005102020%20changes%20marked%20in%20yellow.pdf.

25 Baseball arbitration arose as an alternative to free agency for professional baseball players. Players and teams could request salary arbitration utilizing a three-member panel. Both parties would submit their proposed salary based on evidence like for example, team record, player performance, fan appeal, past compensation, and comparative salaries. The panel is only empowered to accept the proposal they deem most realistic, it may not "split the baby" or award a salary other than the amount requested by a party. The award is final and is issued without explanation.

26 The "safety net" feature is important: there are many circumstances in which two parties may prefer to enter into an alternative licensing arrangement, including cross-licensing deals, rather than opting for the Standard License Agreement (explained below). The ILP does not interfere with existing incentives to enter into such alternative deals.

27 Parties can always deviate from the SLA and negotiate a bilateral agreement. However, this cannot become part of a baseball arbitration.

This creates a strong incentive for each party to remain fair and reasonable.[28] By rewarding the parties for reasonable claims while penalizing unreasonable positions, the process helps to eliminate inflated claims. The established royalty is final and binding. Changes are only possible if the value of the trait changes substantially. The resulting valuation is likely as close to the true value of the technology as possible, or as noted by Lemley and Shapiro: "The Nash equilibrium of the game should be for each party to [submit a royalty] equal to the true value of the [patent]".[29] The ILP's incentive to reach an agreement bilaterally is strong: After eight years of ILP practice, the baseball arbitration mechanism has not yet been triggered. However, several license agreement and portfolio swaps have been established.

- **The Expert Committee**: The independence of the Expert Committee is essential for the acceptance of the ILP. The seven experts collectively have expertise in IP, economics, vegetable seed market, plant science, and accounting, and are independent.[30] Their selection is based on a unanimous proposal of the ILP Board and needs to be confirmed by at least 2/3 of the Members.

- **Most Favored Nation Clause**: The ILP provides for a Most Favored Nation ("MFN") clause, that is, each Member is entitled to obtain a license under the best terms granted to any other Member under the SLA. Once an MFN percentage has been set, either by baseball arbitration or after bilateral negotiations of an SLA, any licensee may request to enter into an SLA with the MFN percentage.

- **Other Elements:** Every interested party is allowed to join. Ownership of patents is not required. ILP members are free to in- or out-license outside the ILP. They can freely choose which ILP patents to in-license. No "bundling" of patents occurs. Several other elements safeguard the pro-competitive effect of the ILP, for example, members are always free to challenge the validity of ILP patents.

  By enabling access to traits at low transaction costs, the ILP provides "*free access but not for free*". The use of fair and non-discriminatory licensing conditions in addition to transparent and pragmatic procedures are key for the broad acceptance of this platform by a stakeholder group with diverse interests.

More information on the ILP is available under: https://www.ilp-vegetable.org/

3.3 MATERIAL TRANSFER AGREEMENTS (MTAS) AND CONFIDENTIAL DISCLOSURE AGREEMENTS (CDAS) TO PRESERVE OPEN ACCESS

This section is applicable for GRs and GR-derived digital sequence information (DSI), which have not yet reached the maturity of an innovation or a product which can be protected by patents or PBRs, if a GR or GR-derived DSI is intended to be broadly disseminated with a clear intent to keep the afore-mentioned asset(s) unencumbered by third party IP rights.

In these cases, there is a substantial risk that an unconditional dissemination of the GR material or an unconditional disclosure of the GR-derived DSI may enable others to create and protect innovations. The resulting IP rights may substantially limit and restrict the

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[28] The experts cannot propose an average. If one submission is unreasonable, automatically the other is adapted. In addition, the "losing" party has to pay the costs for the arbitration (30.000 €).

[29] Lemley MA and Shapiro C (2013) "Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents", Stanford Public Law Working Paper No. 2243026. Available at: http://ssrn.com/abstract=2243026.

[30] In the five years before their appointment, an Expert Committee member is not allowed to have been (i) a board member, secretary or expert; or (ii) a shareholder, an employee – or had a special interest in or other relationship – with a vegetable breeding company.

use of the original GR or GR-derived DSI. It may make the use by third parties unattractive. Therefore, there should be an upfront consideration whether to share the GR material and GR-derived DSI only under conditions which prevent such encumbrances. The risk to safeguard the confidentiality of a GR-derived DSI (or other information) and GR materials is reduced once registered IP rights (patents or PBRs) are obtained. Then, licensing of the IP right (see Chapter 3.1 and Chapter 3.2) or a public technical disclosure (see Chapter 3.5) usually become the predominant options.

An owner of such IP assets may adopt a strategy to preserve open access for various reasons. A genuine desire to broadly distribute a GR for the common good is one, such as where the GR product is a cure for disease. Another may be that law applicable to the GR source requires it. A third, more mercenary, reason is where broad adoption of a GR-related product or process will create a market for an ancillary product sold by the owner (for example, to make an herbicide-tolerance trait freely available to promote the use of the herbicide). Regardless of the reason, the strategy is only effective if third parties can be prevented from obtaining IP rights that would inhibit the use of the freely distributed IP assets.

While Open Source (OS) models have been successfully established in software, their use in other technology areas has been scarce and – in most cases – less successful. One key reason is that, for software, open-source requirements can be enforced on the basis of copyright, an IP right which does not require registration but is established by the act of creation. A similar "unregistered IP right" does not exist for GR-related innovations, as trade secrets are inherently incompatible with any open access and open-source strategy. To some extent "access right" based approaches have been used (see below). The following points should be considered in the context of such a scenario:

(i) **Primary Intent:** To implement an open access strategy while precluding third parties from using the GR material and information to establish their own IP and constrain the freedom to operate (FTO).

(ii) **Options:** Several options are available, including MTAs and CDAs in various forms, mutual non-assert agreements, or frameworks for protected commons.

(iii) **Critical Questions and Considerations:** For choosing the best possible option, several questions need to be addressed prior to any engagement with third parties.

- **What rights do you have already which provide a basis to enforce rights and obligations?** In case there is no registered IP right and the owner of the information or material only has a right to regulate access, enforceability will solely rely on the access contract. However, a breach of contract (for instance, transferring the asset to a third party) can be difficult to prove.

- **What is the scope of use under the agreement?** CDAs and MTAs are usually only used for research, that is, non-commercial purposes. Commercial license agreements (see Chapter 3.1) which are solely based on non-registered IP rights are in principle possible, but difficult to manage and enforce. Also, it is usual for commercial license agreements to include confidentiality and material transfer provisions where appropriate instead of using separate CDAs and MTAs.

- **Full open access or protected commons?** Open access is often best served if the receiving party commits not to file for IP rights on the received assets and any improvement or use thereof. However, in such a case, a user will often keep their improvement secret. In addition, an attempt to prevent acquisition of IP rights is often incompatible with business models which require IP rights for sustainability.

Alternatively, one can allow for certain IP rights (for example, PBRs/PVPs), which protect a specific embodiment but do not prevent further development – however, they prohibit patents. A further alternative would be a mutual non-assert where all open access licensees commit not to assert patents on improvements against other open access licensees. Such mutual non-asserts have been implemented in practice by the BiOS initiative, the International Licensing Platform Vegetables, and other initiatives discussed (see Chapter 3.2).

- **What kind of license do you want to grant?** Open access licenses are by character non-exclusive and usually granted under an open licensing framework with standard license agreements.

- **What rights to you want to transfer?** What limitations should apply? Usually, open access licenses are global. As all parties have access and the non-assert usually only binds direct parties, there are no sublicensing rights, other than to make and use the product designed by the original licensee (restricted sublicenses).

- **What obligations for the licensee should apply?** Usually, open access licenses have no obligations for monetary benefit-sharing. However, the following obligations may apply:

  (a) Restrictions on IP right filings,

  (b) Mutual non-assert of any background and/or foreground IP right against other open access licensees

  (c) Requirement to report and publish improvements.

- **What risks need to be managed?** The licensor will usually limit risks which arise from a licensee's use of the GR and innovation. Associated risks should be managed with clauses regulating liability and indemnification. In addition, there need to be clauses which address the risk that the licensee breaches the agreement or becomes insolvent. Usually, such risks are managed with clauses providing a right for the licensor to terminate the agreement. Insolvency provisions are still necessary even in a license with no monetary consideration because the license, as an asset of the debtor, could be assigned to an unacceptable third-party creditor.

(iv) Examples and Template Agreement:

- Suitable license and material transfer agreements (including the standard material transfer agreement (SMTA) under the International Treaty for Plant Genetic Resources for Food and Agriculture) can be found here: https://www.wipo.int/tk/en/databases/contracts/list.html

3.4 TRADE SECRET LICENSING STRATEGIES FOR GRS

This section is applicable if a GR, related DSI, or certain findings related to their utilization are (i) not publicly available, and (ii) not (or not yet) in a development stage which allows for a registered IP right or where a registered IP right is not possible (legally, financially, or for other reasons) or strategically not meaningful as – for example – enforcement is *de facto* impossible. **In the area of GRs, this is a very common situation**, especially in the middle phases of a GR-based development project (see also Figure 2). At the beginning of a GR-based development project, where the asset is essentially just the GR-material, trade secrets are difficult to argue or establish, as usually the GR-material will be considered publicly available. Likewise, at the end of a GR-project, where the GR-derived product is commercialized, trade secrets will usually not apply, as the product will be publicly available, although in rare situations trade secrets may apply where the product is not easily reverse-

engineered or the process for making the product is secret. However, at the stage of GR-derived sequence information and innovation, trade secrets may apply and can often also be combined with other IP rights, such as patents or PBRs.

However, trade secrets are also the most difficult IP right to manage, and secrets are *in fact* the most sensitive IP rights. While there are no filing costs, it does not mean trade secrets are "for free". On the contrary, in view of the impact on internal efforts to keep the secret, it comes with significant restrictions on cooperation and other strategic development options for the GR. In addition, any effort to license trade secrets can be destroyed by inadvertent or intentional public disclosure of the trade secret. All this makes trade secrets likely the "costliest" IP right.

Eventually, trade secret agreements are special confidentiality agreements and/or material transfer agreements (see Chapter 3.3) which are used in situations where the IP asset is of very high value, but where filing of a patent or other registered IP rights is not (or not yet) possible.

Trade secret license agreements are rare, because such a license requires sharing the secret, which often is the end of secrecy. Nevertheless, trade secret license agreements are possible and sometimes unavoidable when it comes to developing a trade secret into a commercial product. In an ideal scenario, a trade secret is only a temporary IP right that is later replaced with a registered IP right, for example, a patent or plant breeders' right.

The following points should be considered in the context of such a scenario:

(i) **Primary Intent:** Often, GR-related materials and information are not (or not yet) in a form which allows for registered IP rights. In addition to the specific rights granted under biodiversity or ABS legislation, often only trade secrets can be used as a basis for license agreements and benefit-sharing. Thus, the purpose of this section is to outline how to manage licensing of or collaboration with material and information that is not (yet) patentable.

A key objective of any trade secret agreement is to keep its subject matter secret. While there are remedies against the breach of trade secrets, the enforcement of such rights will not provide a cure for the breach: Once a trade secret is disclosed, it is lost. Damages are often hard to prove, and reparation is difficult to obtain. Litigating a case of breach of a trade secret license is as frustrating as litigating a murder case: You may succeed to penalize the culprit, but you will not be able to revive the corpse.

(ii) **Critical Questions and Considerations:** Several questions need to be addressed prior to any engagement with third parties on trade secrets.

- **Are you – in principle – qualified for trade secret protection?** Trade secrets require that the information is valuable, is secret or not commonly known, and reasonable measures have been taken to protect its confidentiality. It may depend on your country's laws whether, beyond information, tangible materials can be subject to trade secret protection.

- **Can you sustain trade secret status?** Trade secrets require reasonable measures to protect its confidentiality. This may include the following:

(a) Legal ability to restrict access: Especially public institutes need to carefully validate whether under the applicable access-to-information acts access of third parties to information can be denied.

(b) Technical ability to restrict access: This includes access to premises but also to information management systems. Again, for public institutes, a complete denial of access might be a challenge.

(c) Need-to-know access: If all employees or institute members have access to the secret information, such information will hardly qualify as a trade secret. In consequence, access needs to be limited to as few people as possible. It also needs to be ensured that all people with access are bound by agreement (for example, employment agreement) and that ideally access to information is monitored and recorded.

(d) CDAs: People with access to the secret need to be bound by strict agreements. There could be problematic situations where students or other non-employees have access or where the confidentiality requirements conflict with academic freedom to publish.

– **Is trade secret protection the only available IP tool and/or are other IP rights better suited to protect your innovation or asset?**

Whether to rely on trade secrets or – for example – patents may depend on several factors:

– **Can an enforceable patent be obtained?** Sometimes patents, especially related to methods of production or research tools, can be difficult to enforce, especially if they do not leave any "fingerprint" in the resulting product, that is, any specific indication that the method or tool has been used. In these cases, it might be difficult to obtain evidence for infringement, especially in countries where legal instruments for evidence collection like discovery or *saisie-contrefaçon* are not available. In these scenarios, trade secrets might be more favorable than a patent.

– **If an enforceable patent could be obtained, how valuable is the asset in relation to the patent filing costs?** The patent costs will be largely influenced by the number of countries the patent is filed in (translation costs), the number of pages, and the number of claims. The costs can easily accumulate to several hundred thousands of US dollars for a normal life science related application. As a rule of thumb in the life science industry, the costs for a patent strategy (incl. filing, prosecution, and maintenance costs) should not be more than 5% of the total profits generated from the protected assets.

– **What is the expected lifecycle of the asset in relation to a patent term?** As a rule of thumb, a patent is only meaningful if the expected technology lifecycle of an invention is at least five years, preferably at least 10 years. Before being granted, examination of the patent usually takes more than five years, in life science cases often more than seven years, and only after grant a patent provides an enforceable right. If by that time the innovation is already outdated, the costs for obtaining a patent are essentially wasted. Therefore, for innovations of a short lifecycle, trade secrets or the simpler know-how[31]

[31] When referring to unpatented information, the terms "trade secret", "know-how" and "proprietary information" are often used interchangeably. Use of the mere word does not provide any legal definition, so in any agreement it must be defined. In practice, a trade secret is information that can be defined with some particularity. In contrast, know-how is information which is not as easily defined but also has value, such as accumulated experience. Proprietary information broadly encompasses the foregoing as well as any information the possessor considers of competitive value. Genetic sequence information for a product might be a trade secret

protection should be considered as alternatives. In some countries, also utility models might be available.

- **Can the trade secret be reverse engineered from a commercial product?** One critical point whether to opt for trade secrets or patents is the question of whether or not the trade secret can be reverse engineered from the commercialized product. For example, a GR-derived sequence can today be identified in a final product without major efforts. Genome sequencing is often available at high quality for less than USD 1,000. In these cases, a trade secret strategy is not sustainable, often risky, and patent filings or technical public disclosure should be considered as alternatives.

- **What kind of license do you want to grant?** In theory, licenses to trade secrets can also be exclusive or non-exclusive. However, in contrast to patent licenses, non-exclusive trade secret licenses to multiple licensees are rather uncommon as this increases the risk of "leakage" and loss of the trade secret. Thus, trade secrets should only be licensed to one or very few parties.

- **What rights do you want to transfer?** What limitations should apply? With respect to rights, especially (i) the field of use and (ii) the territory are of importance. Sublicensing and further disclosure is usually specifically prohibited. Keep in mind, that few licensees will be able to utilize a license on a global scale. To ensure broad dissemination, country-specific licenses should be considered.

- **What obligations for the trade secret licensee should apply?** In addition to requirements to take all commercially reasonable measures to ensure the confidentiality of the trade secret, trade secret licensees usually have obligations for monetary sharing of benefits arising from the exploitation of the trade secret (milestone payments and/or royalties on net sales) and other obligations similar to other license agreements (see Chapter 3.1).

- **What risks need to be managed?** The primary risk is the disclosure of the trade secret, whether deliberate or negligently. As damages resulting from the disclosure are often difficult to prove, it should be considered to implement a liquidated damages payment, that is, the payment of a fixed amount that compensates the trade secret owner for the loss of all future income as the trade secret is not public. However, licensees will usually refuse to accept a liquidated damages provision. They may accept an initial payment obligation and a minimum royalty payable under the agreement. Those amounts should equal the value of the trade secret in the event the license must be terminated for inadvertent or intentional disclosure of the trade secret.

  Another critical risk is that a third party files a patent application claiming (a part of) the subject matter of the trade secret. Such filing could be the consequence of an unintentional disclosure, a breach of confidentiality, but also of serendipitous parallel discovery. In any of these cases, said third party filing may compromise the (former) trade secret owner's freedom-to-operate. To mitigate the risk, trade secret owners are well advised to combine their trade secret strategy with a strategy to protect their **prior-user-rights**. Many countries provide a user the statutory right to continue the use of an invention when that use began before a patent application was filed for the same

of value, but the know-how involved in scaled up manufacturing of such product could be more valuable as it would put the licensee into business more quickly.

invention. Prior user rights are provided for by the different national legislations and such provisions in national legislation only have national effect. The scope and conditions differ from country to country.[32] However, one critical common prerequisite is the proper documentation of the prior use. The documentation needs to be sufficiently granular and should indicate all critical features of the invention including the scope and location of use. The documentation of a prior use should be deposited with a public notary or an alternative deposition mechanism, such as i-DEPOT provided by the Benelux Office of Intellectual Property[33] or other similar available services.

Other risk mitigation measures are similar to other license agreements (see 3.1) and include clauses regulating liability, indemnification, termination for breach and insolvency.

(iii) Examples and Template Agreement:

- Trade Secret License Agreement on Ostri Pheromone to attract Ostrinia Furnacalis: https://www.wipo.int/tk/en/databases/contracts/texts/2019_07_license_agreement.html

3.5 PUBLIC DISCLOSURE: PRIOR ART STRATEGY

This section is applicable to prevent encumbrance by third party IP rights for a GR, GR-derived DSI, a GR-related IP right or product.

In contrast to Protected Commons (Chapter 3.3), this approach solely relies on the effect of prior art. The term “prior art” refers to the entire body of knowledge which is available to the public before the filing date or, if priority is claimed, before the priority date, of an application for certain industrial property titles, principally patents, utility models and industrial designs. The identification of prior art constitutes a cornerstone for the substantive examination of applications for these titles, since requirements such as novelty and inventive step are established by comparing the claimed subject matter with the relevant prior art. In consequence, the prior art effect is stronger if the innovation is more mature. The mere disclosure of a GR and related DSI usually does not create a prior art which effectively prevents patenting of subsequent innovation, as it often would not be considered an enabling disclosure. In cases where it was desired by the custodians, it has been reported that creating written prior art can be helpful when it comes to creating prior art for informal, uncodified traditional knowledge (TK) which otherwise would be difficult or impossible to find for examiners. The publicity effect of prior art documentation influences whether it protects prior user rights or prevents third party patents in general.

The following points should be considered in the context of such a scenario:

(i) Primary Intent: How to create robust prior art to prevent third parties to capture your invention or material.

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[32] WIPO Doc. SCP/20/6 (Oct. 21, 2013), Standing Committee on the Law of Patents, Twentieth Session, Geneva, January 27 to 31, 2014, EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: PRIOR USE https://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_6.pdf

[33] If you have new ideas or develop concepts, formats or software regularly, you can record your creations in the Benelux Office of Intellectual Property (BOIP)’s i-DEPOT. The i-DEPOT platform assigns an official date stamp to your idea. This provides you with proof that your idea, concept, (fashion) design, prototype, film, lyrics, screenplay, etc. were already in existence on a certain date. See under https://www.boip.int/en/entrepreneurs/ideas/good-idea-store-it-in-an-i-depot#i-depot-trade-secret-and-know-how

(ii) Critical Questions and Considerations: Several questions need to be addressed prior to any engagement with third parties.

- **How mature is the innovation / art?** Usually, GR material and raw DSI are considered rather immature "discoveries". Their disclosure will not necessarily anticipate or destroy the novelty of subsequent innovations. Annotated DSI are more mature, here the annotation may preclude patents on uses which are obvious in view of the annotation. TK could in fact be quite specific when it comes to the use and benefits of a GR. This TK is often in an informal (non-codified, non-written) form.[34]

- **What is your intent?** The intent could be (i) to protect only your own interest, that is, prior use(r) rights, but not to disclose the information to everybody else or (ii) to prevent any encumbrance by third party rights. Both intents require different strategies: The first requires protecting prior user rights, the second requires creating broad public prior art through legally certain technical public disclosure.

- **How and where to document the prior art and/or prior use?** The existence of a prior art or prior use can be documented in a public or non-public form. If the intent is to prevent any third-party patents, a legally certain technical public disclosure ideally in a recognized prior art depository is most effective[35].

  A prior art or prior use can also be registered without publicity. Here a deposit with a public notary or with online services or platforms can be helpful.[36] For electronic deposits, it is important to ensure an electronic unique ID or timestamp.

3.6 COLLABORATION STRATEGY

This section provides guidance on how to establish a fruitful collaboration strategy.
A collaboration strategy is most appropriate for the development of an innovation if (i) the cooperating parties have complementary skills or resources, which only in combination enable the development of the innovation, and (ii) have non-competing interests, for example, by operating in different territories, or on different levels of the value chain.[37]

(i) Primary Intent: How to co-create, establish and manage GR-related collaborations.

(ii) Critical Questions and Considerations:

- **Does your potential collaborator have common goals and non-conflicting interests and how does the scope of the collaboration need to be defined to avoid conflicts?** It is important to verify that the goals of all the collaborators

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34 See, WIPO. "Documenting Traditional Knowledge – A Toolkit", 2017. Available at: https://www.wipo.int/publications/en/details.jsp?id=4235

35 For example, IP.com provides a service for so-called "defensive publications": Ip.com's Prior Art Database (PAD) is a large online prior art disclosure service. It is searchable by examiners, inventors, attorneys, research and development teams, and university personnel worldwide. It also provides technical disclosures to patent offices around the globe. When you publish in IP.com's Prior Art Database, a publicly disclosed description of an invention becomes available as prior art on its publication date. For details see: https://ip.com/products/prior-art-database/

36 For example, the i-Depot platform of the Benelux IP Office (https://www.boip.int/en/entrepreneurs/ideas/good-idea-store)

37 A collaboration may also arise between a party fully capable of developing an innovation but without marketing capability and a party with experience and ability to market a developed innovation. The latter party often contributes valuable insight in making the innovation market ready or in obtaining regulatory approval.

are largely aligned. Issues can arise if one collaborator is a for-profit-company, and the other is a non-profit company or an entity focusing on public good. While sometimes conflicting interests can be aligned (for example, by defining spheres of interest in industrialized countries vs. low- and middle-income countries or other distributions), the different goals can often create conflicts when it comes to patenting strategy and enforcement of rights. The same may happen if the parties are interacting in the same business area and in the same territory. Here often collaborations are only possible if they are limited to pre-competitive innovations, that is, innovations which do not directly lead to products but to technologies which only enable products (such as new genes for disease resistance). It is therefore critical to define the goal and scope of the collaboration in a way to minimize potential conflicts-of-interests.

- **Do the collaborators have complementary skills and resources?** The development of innovations requires certain skills and resources, not only in science and technology, but also in regulatory, legal, IP, and project management. In addition, resources including people (described in 'Full Time Equivalents', or FTEs), rooms and facilities (for example, laboratories), equipment (machinery), and financial resources are required. The resources required for a project need to be carefully mapped prior to the project and it needs to be decided which collaborator contributes what. Ideally, there should be neither gaps nor overlaps.

- **How to fairly allocate costs, risks, rights, and benefits?** A lack of clarity regarding the allocation of costs, risks, rights, and benefits can often lead to tremendous struggle or even litigation, especially if a project is successful. Such allocation should not be left open or to "the laws", as laws may often differ from country to country. For example, leaving the ownership to the inventorship laws of the countries of the collaborators can often create disputes because the standard of when a person would be considered inventor is not necessarily always clearly defined. Attention should be paid especially to the following points:

    - Who should contribute which resources (FTE, rooms and facilities, equipment, costs, other in-kind contributions)? Who is accountable for which activities (research, IP filing, regulatory filings, etc.)?

    - Who should legally own the resulting IP rights (foreground IP)? Who should pay for the foreground IP costs? Who has what rights under the foreground IP?

    - What kind of background IP is available and under which conditions for the project and for the commercialization of the resulting products (including foreground IP)?

    - How should the income from the licensed products (covered by the foreground IP) be shared?

    - How are risks and liabilities regulated?

    - Who owns the generated foreground IP on termination of the Agreement?

    - Which laws apply to the agreement? What would be an acceptable "neutral" law for the agreement and for dispute mediation? What kind of dispute mediation is preferred – courts or arbitration?

- With collaboration agreements, care must be taken to avoid violations of competition laws. It is beyond the scope of this paper to address all competition law issues potentially arising from collaboration agreements. If the parties are competitors in the same geographic or product market, or even vertically related in the same supply chain, the foreground IP resulting from the collaboration, regardless of which party may own it, should be freely useable by both parties in their respective businesses, and each party should be free to license its foreground IP to third parties without prior approval of the other party.

(iii) Sources

http://www.1000ventures.com/doc/legal/agreements_list.html