Draft Intellectual Property Guidelines for Access to Genetic Resources and Equitable Sharing of the Benefits arising from their Utilization

CONSULTATION DRAFT

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BACKGROUND

This draft document is a shortened, more accessible version of document WIPO/GRTKF/IC/17/INF/12 ("Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing: Updated version").

It may be worth recalling that document WIPO/GRTKF/IC/17/INF/12 is the updated version of document WIPO/GRTKF/IC/7/9 ("Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing"). Document WIPO/GRTKF/IC/17/INF/12 was prepared by the Secretariat at the invitation of the sixteenth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), held in May 2010, and was made available, as an information document, for the seventeenth session of the IGC, which took place in December 2010.

Document WIPO/GRTKF/IC/17/INF/12 is available at:
http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_inf_12.doc

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http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_9.doc

This version has been prepared by the Secretariat of WIPO in order to facilitate comments.

This draft is published for consultation. Comments would be appreciated and may be sent to grtkf@wipo.int.

EXECUTIVE SUMMARY

In the countries that are Parties to those international instruments, any access and benefit-sharing arrangements should conform with the existing international framework, which is essentially set by the Convention on Biological Diversity (the CBD), the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) and the International Treaty on Plant Genetic Resources for Food and Agriculture (the International Treaty).

International legal standards for access to genetic resources (GRs) require prior informed consent and equitable sharing of the benefits arising from the utilization of GRs.

Intellectual property (IP) issues arise as one element of this broader framework on access and equitable benefit-sharing. IP management in an access and benefit sharing agreement can greatly influence the degree to which the access provider and the resource recipient can achieve their goals and serve their mutual interests.

These draft guidelines are not intended to promote any particular choice to use IP rights, or to avoid their use, in the context of access and equitable benefit-sharing.

These draft guidelines provide practical information for providers and recipients of GRs and relevant policy and legal information. They illustrate the practical IP issues that providers and recipients are likely to face when negotiating an agreement, contract or license, and thereby enhance the information available to stakeholders assessing their IP options when considering access and benefit-sharing. They have informal status only, and do not offer authoritative legal advice nor set a policy direction.

The present document introduces into the context of agreements on access and equitable benefit-sharing, and the role IP plays (Part I), sets out the main ideas behind the guidelines in its general provisions (Part II) and identifies the main preliminary steps for IP negotiations (Part III). In its main part, it develops the specific IP issues (Part IV) including overall IP issues (A), specific IP rights and issues (B) as well as licensing issues (C). Further, it refers to Model IP Clauses (Part V) and adds some considerations for developing sectoral approaches (Part VI).

I. INTRODUCTION

Definitions and use of terms

These draft guidelines are for general reference, so no precise definitions are intended, and the use of terms is not intended to have any legal effect. Contracts or agreements can settle on their own definitions of key terms, with reference, for instance, to the customary laws of indigenous peoples and local communities.

Definitions of the key terms related to IP and GRs used in this document can be found in the "Glossary of Key Terms related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions", information document prepared by the WIPO Secretariat, which is available at: http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_23/wipo_grtkf_ic_23_inf_8.doc.

Information on IP is available at: http://www.wipo.int/about-ip/en/.

Access to GRs and the Fair and Equitable Sharing of Benefits arising from their Utilization (also referred to as Access and Benefit-Sharing or ABS)

International legal regimes[1] and many national laws have been developed to regulate access to GRs, in particular since the negotiation of the CBD.

According to the CBD, 'access [to GRs], where granted, shall be on mutually agreed terms' and 'shall be subject to prior informed consent[2] of the Contracting Party providing such resources, unless otherwise determined by that Party.' Also, when GRs are obtained or accessed for research or commercial purposes, the benefits from any research, development and commercial use should be fairly and equitably shared with the providers of the resources. This is the basic legal framework for access and benefit sharing for GRs under the national sovereignty of the many countries adhered to the CBD. Within this framework, drawing up a contract, agreement or licence is one way of expressing the 'mutually agreed terms'.

In essence, a contract is a promise or undertaking containing generally mutual obligations of the provider and recipient that can be enforced by law.

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[1] The international legal framework is mainly composed by the Convention on Biological Diversity (the CBD), the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) and the International Treaty on Plant Genetic Resources for Food and Agriculture (the International Treaty).

[2] The need for prior informed consent from the appropriate individuals and institutions should also be accounted for. For potential users of genetic resources, this includes ensuring legal compliance with any access and benefit-sharing regimes that national governments, local authorities or local customs have established.
Detailed guidelines for such prior informed consent procedures have been spelled out in the Bonn Guidelines and are contained in several guidelines and model agreements. For an example, see Micro-Organisms Sustainable Use and Access Regulation International Code of Conducted (MOSAICC), Updated September 2009, Section 1.1, available at: http://bccm.belspo.be/projects/mosaicc/docs/code2009.pdf

In general, the terms and conditions of the contract, agreement or license relating to access to GRs define the purpose and permitted uses of the accessed resources, including the benefits that the provider is to receive from the recipient.

In some cases, a national law on GRs might specifically require that the provider and recipient agree on an access contract – and in that case, the law might lay down particular conditions that the contract or agreement has to comply with[3].

If there is no specific law for access and benefit-sharing, a contract is likely to be governed by general background laws such as the law of contracts and competition law. For example, under many national laws of contract, a contract or agreement cannot be enforced if it has been obtained by coercion against the will of either party, or through deception or fraud.

Typically, a provider of a resource (such as an indigenous community, a government agency, a research institution, or the owner of land on which the resource is) reaches an agreement with a resource user (such as a researcher or a company that wants to use the GRs.) Such agreements can refer to the intended use of the resources, any restrictions on the use, and the way any benefits resulting from the resource are managed and shared. They generally operate in line with other laws regulating the environment, public resources, indigenous and community rights and regional development, as well as general contract and property law.

At the national, regional and community level, a range of laws, regulations and policies implement this framework, and govern directly how GRs are accessed and used.

What is the role of IP in access and benefit-sharing?

When research is done on GRs, this can result in inventions that can be eligible for IP rights such as patents.

Therefore, negotiating and granting access to GRs, for research or commercial uses, can raise IP questions: Should IP rights be used? If so, under which conditions?

The arrangements made for managing IP can influence the overall results of access to GRs. They can be important in ensuring that an access agreement actually creates benefits, and that benefits are shared equitably, respecting the interests and concerns of the resource providers.

What are the typical IP issues to be managed?

Several options exist on how to manage IP issues. In very broad terms, these options include the following:

- to avoid IP rights, which implies that access to GRs is subject to agreement not to seek IP rights on the material received;
- to vest IP rights in the custodian of the GRs or to jointly own such IP rights; or
- to give rights derived from the use of the resources to the user, subject to various conditions and safeguards, such as rights to receive benefits such as royalties and other payments, access to benefits of research, involvement in community-based development initiatives, contribution to various forms of appropriate social and economic development, and reporting and disclosure obligations.

[3] See document WIPO/GRTKF/IC/5/9, Section IV; e.g. Brazilian Provisional Measure No. 2.186-16, of August 23, 2001

Issues dealt with in agreements include:

- the entitlement to seek IP in inventions and other results of research using the resources
- the ownership and licensing of any such derivative IP
- the responsibility for maintaining and exercising IP rights
- the arrangements for distributing any financial or other benefits resulting from this derivative IP.
- the requirement for the recipient of the resource to report on any IP that is applied for, and similar developments.

II. GENERAL PROVISIONS

What is the purpose and scope of these guidelines?

These draft guidelines provide background information and guidance about IP aspects of access and benefit-sharing. They may serve both providers and recipients of GRs when they negotiate, develop and draft the IP elements of mutually agreed terms for access to GRs and benefit-sharing.

The diversity of national laws and of the practical interests of providers and recipients is likely to lead to a wide range of choices when actual provisions are negotiated and drafted. These guidelines do not prescribe one template or set of choices, neither to they seek to pre-determine actual choices.

Since the IP issues are only one component of the full range of practical and legal questions that may need to be addressed in access and benefit-sharing scenarios, these guidelines should be seen only as supplementary and subordinate to the general principles and legal regimes that cover access and benefit-sharing for GRs. They are an adjunct and an aid, to be used as a resource, rather than stand-alone guidelines to negotiating and concluding contracts and agreements on access and benefit-sharing.

These guidelines have informal status only, and do not offer authoritative legal advice nor set a policy direction. They are voluntary and illustrative only. They are no substitute for relevant international, regional or national legislation.

These draft guidelines cannot substitute for specialized legal advice. Prior to entering into any legally binding contractual arrangement setting out mutually agreed terms of access to GRs and benefit-sharing, all contracting parties should seek expert legal advice.

Indeed, in any particular transaction and collaboration, the nature and terms of a contract can be tailored to fit the needs of the two partners to create an optimal partnership. In any event, in any potentially legally binding relationship, all parties should normally seek individual advice. Such individual advice cannot be obtained from a consideration of the model or actual agreements of other institutions or organizations; the more the specific relationship under development is taken as the starting point for contractual negotiations (rather than other agreements developed in other contexts), the more likely that the resulting agreement will be workable and mutually beneficial.

Further, nothing in the draft guidelines should be interpreted to affect the sovereign rights of States over their natural resources, including their entitlement to set terms and conditions on access and benefit-sharing.

What methodology has been used to develop these draft guidelines?

These draft guidelines draw on practical experience in a very wide range of access and benefit-sharing scenarios, and provide illustrations of issues that have actually arisen in practice and the various approaches taken to resolving them.

They draw on a wide range of inputs, in line with the requirements established by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the Committee). These include inputs from WIPO's Member States and from other stakeholders in response to questionnaires circulated under the authority of the Committee.

The sample clauses contained in these guidelines as examples are meant to illustrate current licensing practices and are taken from model and actual agreements reported on in previous documents and updated by new submissions[4]. They do not have any normative value but show different options for possible IP clauses.

What is the relationship to other instruments and forums?

The guidelines take into consideration the work of relevant international agreements and institutions such as the CBD, the FAO ITPGR, the FAO Code of Conduct on Germplasm Collection, and the recommendations of the World Summit on Sustainable Development ("WSSD") held in Johannesburg in September 2002 in relation to the need to develop practical measures to promote and safeguard the fair and equitable sharing of benefits arising from the use of GRs and associated TK, innovations and practices.

In particular, it is worth noting that:

- The Nagoya Protocol[5] (to the CBD), a new international regime governing the use of GRs, has been adopted in October 2010, but is not yet in force.

- The FAO ITPGR has developed a Standard Material Transfer Agreement (SMTA)[6] concerning the plant GRs covered by that treaty.

III. PRELIMINARY AND BASIC STEPS FOR THE NEGOTIATIONS

It is important to prepare negotiations in advance and parties may consider some of the following indicative and illustrative preliminary steps and factors of negotiations to enhance a mutually agreeable and practically workable agreement.

Before negotiations or discussions occur between a provider of GRs and a potential recipient seeking access to the genetic resource, both parties should seek to understand and acknowledge the legitimate interests and objectives of the other party. The agreement

[4] WIPO has developed an on-line, searchable database of biodiversity-related Access and Benefit-Sharing Agreements and related information, which is available at: http://www.wipo.int/tk/en/databases/contracts/index.html.

[5] The text of the Nagoya Protocol is available at: www.cbd.int/abs/text.

[6] For further information, see: www.planttreaty.org/content/what-smta.

should try to capture and express a common understanding of shared interests and objectives.

In some negotiations involving parties with diverse backgrounds, the identification of interests can entail building respect, trust and understanding for the values and cultural backgrounds. This applies as well to settling the IP provisions within an agreement.

An approach to IP issues that promotes the common interests of the two parties is recommended. The final understanding reached must be good for both parties if it is to form the basis for a lasting, beneficial relationship and mutual trust.

STEP 1: CONSIDERING A PRELIMINARY CONFIDENTIALITY AGREEMENT

Potential recipients and providers may enter into a preliminary confidentiality agreement to explore potentially common interests and to conduct the assessment of resources. If they then identify mutual interests, a separate access and benefit-sharing agreement may then be negotiated.

Preliminary confidentiality agreements are important to protect confidential information during the assessment and negotiations.

STEP 2: DEVELOPING A SHARED UNDERSTANDING OF THE VALUE OF THE CONTRIBUTIONS

One key to an equitable and enduring partnership, and appropriate provisions concerning IP, is a shared understanding of the value of the contributions that are made by each party – on the one hand, the value of GRs (and eventually associated TK) that are being provided and, on the other hand, the value of research, development, risk management and investment that is involved in the use of the resource.

Each party may need to understand the limitations of their contributions to the potential arrangement, as well as the valuable attributes of their contributions. It will be helpful for both parties to recognize the different expectations and perceptions of value that each brings to the discussions.

A shared understanding of the value of the contributions made by each party can greatly increase the likelihood that expectations will be reasonable and that relationships formed will lead to positive outcomes.

Tips for the recipient to understand the provider's perspective

A recipient of GRs and associated TK may need to understand that:

- The value of a genetic resource or insight into the workings of biological material (including traditional knowledge) may not be limited to monetary value:
    - The resource and TK, for instance, may be associated with spiritual or cultural values of the provider that cannot easily be defined in economic terms or within a brief time frame.
    - GRs may be the result of many generations of conservation, selection and development by indigenous and local communities. Associated TK may have been developed over generations.
- If the resource provider is a government body, a public agency or a community, broader public interests - e.g. sustainable resource management, environmental protection, social equity, appropriate grass-roots development and technology transfer – are likely to be

valued more highly than more immediate technological or commercial goals. Non-monetary and longer-term benefits may be preferred over short-term or monetary benefits.

Sample Clause 1 exemplifies how the recognition of value could be reflected in the agreement:

Sample Clause 1: Recognition of value of research material

"*This Research Material represents a significant investment on the part of provider, and is considered proprietary to provider, recipient's investigator therefore agrees to retain control over this Research Material, and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of provider*".[7]

Tips for the provider to understand the recipient's perspective

It would be useful for a provider of GRs to recognize and understand the way a potential recipient may evaluate the resources and associated TK. The factors that may be considered include:

(a) *alternative source* factor: What alternative sources exist for the material of interest and what are the costs and conditions of access through those alternative sources?

(b) *proximity to market* factor – the cost, in time, money, and scientific or personnel resources, of R&D investments needed to fashion a product that might be saleable;

(c) *risk of technical failure* factor – What are the prospects for arriving at a revenue producing product from a scientific standpoint?

(d) *risk of regulatory preclusion* factor – What are the prospects for and costs of obtaining regulatory approval to market a final product?

(e) *alternative investment opportunity* factor - Do other investment opportunities exist that offer greater returns or fewer risks?

(f) *authority to consent* factor - Is the provider in a position to give prior informed consent, and is consent also required from other parties or government authorities?

For an example, see Sample Clause 2:

Sample Clause 2: Mutual understanding

"*DTP/NCI has an interest in investigating plants, terrestrial and marine microorganisms and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Organization ("SCO")] in this investigation. DTP/NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to [SCO] in [Source Country] (as the agent appointed by the [Source Country] Government), subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. [SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of [Source Country]'s terrestrial*

[7] Model Material Transfer Agreement (MTA) of the Korean Research Institute of Bioscience and Biotechnology, Clause 6

plants, marine macro-organisms and microorganisms, and selected synthetic compounds subject to the following conditions and stipulations of this Memorandum of Understanding (MOU)".[8]

Mutual understanding of the situation and expectations of each party

Reaching agreement on the value and level of contribution of each party to the access and benefit-sharing arrangement will be vital in ensuring an equitable and effective outcome. There is a wide range of potential factors to be discussed and weighed when assessing the relative contribution of the various parties for a mutual understanding:

- Is a bare resource being provided? or Is there considerable associated TK which provides an important lead for researchers and might increase the chances of a valuable invention?
- Could associated TK contribute so directly and so significantly to an invention based on the resource that the TK provider is actually a co-inventor?
- Is the user of the resource expected to invest heavily in research and development, or is the commercial or technological use of the resource already proven in principle with little additional investment required?
- What kind of products are intended to result from the research and development – for instance, simple reagents for further research, finished medical products, or industrial materials?
- Do the GRs contribute directly to the finished products, or do they provide one indirect input?
- Is the value of the genetic resource proven and well established, or is its potential unclear?
- Should there be an agreement to return to the issue once the actual value of the resource and its potential applications are better known?

STEP 3: REVIEWING RESOURCES AND SETTING GOALS

Before engaging in negotiations on access and benefit-sharing, a provider of GRs and associated TK may need to identify and review systematically the assets it can potentially offer. This assessment may result in an inventory, which could separately account for physical resources and knowledge resources. The legal regimes governing physical resources and knowledge resources may differ, and their legal status are usually distinct, from both IP and valuation standpoints.

Inventory process and potential IP outcomes

The inventory process should assist the resource provider to identify the aims and objectives of the intended access, and the uses to which the GRs and related information (including TK) may be put. It may also identify what the provider does not want to give access to, or what resources could be held in reserve for possible later access, if the partnership develops successfully. The potential IP outcomes of such uses can then be broken down into individual components. This should ensure that, right from the start, the specific IP implications of any access and use have been identified and that, subsequently, any IP rights and benefits arising from the exploitation of those resources can be properly apportioned and managed.

[8] Memorandum of Understanding between [Source Country Organization] and the Developmental Therapeutics Program, preamble

This creates an opportunity for the access provider to identify and achieve broader goals. For instance, this might entail obliging the recipient through the access contract to disclose the origin of GRs in patents resulting from the use of the resources, or restricting permitted use to activities compatible with the cultural values of the provider, or ensuring third party access to research results for non-commercial uses or for use in developing countries.

STEP 4: CONSIDERING DIFFERENT FACTORS AFFECTING AGREEMENTS

In practice, there are many different scenarios involving access to and use of GRs and associated TK. Access and benefit-sharing scenarios can differ in terms of:

(a) *Legal jurisdictions and particular national laws applicable* which may govern the contractual relationship between the parties. This is in line with the sovereign rights of States over their natural resources recognized under the CBD, and the principle that the authority to determine access to GRs rests with the national governments and is subject to national legislation.

An analysis of the relevant international, regional and national laws and regulations, including any *sui generis* legislation on the protection of TK and, where applicable, relevant customary laws in those countries where GRs and associated TK will be accessed, and where IP rights may be developed and exploited, would be useful.

(b) *Providers and recipients:* These may include:

- the government sector (e.g., government ministries, government agencies (national, regional or local), including those responsible for administration of national parks and government land);
- commerce or industry (e.g., pharmaceutical, food and agriculture, horticulture, and cosmetics enterprises);
- research institutions (e.g., universities, gene banks, botanic gardens, microbial collections);
- custodians of GRs and TK holders (e.g. associations of healers, indigenous peoples or local communities, peoples' organizations, traditional farming communities); and
- others (e.g., private land owner(s), conservation group(s) etc.)

(c) *GRs:* A wide range of genetic materials, of plant, animal or microbial origin might be involved: Genetic material may have clear actual value; its potential value may be high; its value may be untested or uncertain; or it may have unforeseen, surprising or unpredictable uses and values in different sectors. Individual agreements may include other materials as defined by the scope of agreement.

For examples of different approaches, see Sample Clauses 3 and 4:

Sample Clause 3: Scope of material

"*Scope of Agreement. This Agreement applies to the use, handling, sale, distribution and any disposition of the Material, Replicates, and Derivatives. For the purpose of this Agreement, "Material" means any material or portion thereof shipped to the Purchaser. For the purpose of this Agreement, "Replicates" means any biological or chemical material that represents a substantially unmodified copy of the Material. Replicates include but are not limited to material produced by growth of cells or microorganisms or amplification of Material.*

For the purpose of this Agreement, "Derivative" means material created from the Material that is substantially modified to have new properties".[9]

Sample Clause 4: Scope of material

"*'Genetic Resource(s)'* means material of non-human animal, plant or microbial origin containing functional units of heredity".[10]

(d) *Agreed or licensed uses of the genetic material and associated TK:* Certain uses may be specifically not permitted, or conditions governing certain uses may be defined, or both. Possibilities range over commercialization (including realizing the market potential of the genetic material and/or TK); research with a commercial objective (in the pharmaceutical, food and agriculture, horticulture, cosmetics and other industries); or scientific or academic research only. Research, selection and development for food and agriculture (in particular within the framework of the FAO ITPGR) may be included.

Sample Clause 5 gives an example of an agreed and licensed use:

Sample Clause 5: Agreed or licensed use of genetic material

"*Subject to the terms and conditions of this agreement and any statutory, regulatory or other restriction imposed by law or any third party interest, recipient may use the material in any lawful manner for academic research, teaching or quality control purposes. Any commercial use of the material requires the prior written authorization of the provider. Such approval will not be unreasonably withheld*".[11]

(e) Time frames within which a particular contract or license may operate: This may set an absolute limit for the licensed use, or establish a timetable for the licensed use, with certain milestones that should be met, and subsequent obligations (such as an agreement to negotiate further terms in the event, for instance, that a product is approved for commercialization).

For an example of time frames set by a model project, see Sample Clause 6:

Sample Clause 6: Time Frames

"*The Hania plant (Withania Somnifera) material will be taken from natural habitat of Karimabad for R&D purposes for 5 years and commercial purposes for next 20 years with permission of the local government , if any. … After expiration of 25 years, the botanical garden will be sole property of local government along with all its moveable and immoveable property*".[12]

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[9] Material Transfer Agreement, American Type Culture Collection (ATCC), Art.1.

[10] Model Material Transfer Agreement (MTA) of the Biotechnology Industry Organization (BIO).

[11] Model Transfer Agreement (MTA): Terms and Conditions of limited non-exclusive license model agreement to use genetic material of the Culture Collection of Dairy Microorganisms (CCDM) of the Czech Republic, Crop Research Institute (CRI), Clause 5

[12] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

Such factors will affect the basic elements of the contract, but will also define and shape the way in which any IP issues are dealt with in a contractual relationship. In some scenarios, there may be no role at all for IP rights.

The following situations could be envisaged:

- An initial agreement may concentrate on non-IP related issues of benefit-sharing, such as research cooperation, evaluation of resources, training and education and technology transfer, and the parties may agree to negotiate a separate commercialization package (including agreement on ownership of IP, right to license the IP, benefit-sharing arising out of any licensing agreement, etc.) at a later date, once initial research leads to commercial possibilities.
- IP rights may have a role to play right from the start of a partnership, often as an integral part of a specific benefit-sharing package, with identifiable short, medium and long-term returns.
- IP rights may be incorporated into a distinct series of licensing terms and conditions that reach beyond the field of access and benefit-sharing, and embrace the wider legal and working relationship of the parties.

STEP 5: CONSIDERING DIFFERENT TYPES OF AGREEMENTS

In practice, negotiators are normally advised to think first about the practical arrangement or partnership that they want to enter into, and then to think about how that arrangement should be expressed in legal terms[13].

For illustration, contractual scenarios relevant to GRs range over the following broad categories or types of agreements:

(a) *Letters of Intent or Heads of Agreement* recording preliminary agreement on the overall framework of a proposed collaboration, including any commercial arrangements that may apply, and to ensure that the future negotiations on the details of a contract or license have a solid basis of understanding. For an example of a letter of intent setting a preliminary framework agreement between a recipient and a provider on plant screening as a basis for further negotiation on possible commercial applications, see Sample Clause 7:

Sample Clause 7: Letter of Intent

"*Letter of Collection*
The Developmental Therapeutics Program ("DTP"), Division of Cancer Treatment and Diagnosis ("DCTD"), National Cancer Institute ("NCI") is currently investigating plants, microbes, and marine macro-organisms as potential sources of novel anticancer and AIDS-antiviral drugs. … While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate [Source Country, SC] organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders.
As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants, microbes and marine macro-organisms worldwide. DTP has an interest

[13] This is often more effective than limiting the range of cooperation and sharing of benefits to a pre-existing model. Earlier agreements and precedents can be used as guidance on the options, without pre-determining the actual choices made by the provider and recipient in any scenario.

in investigating plants, microbes and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Government ("SCG") or Source Country Organization(s) ("SGO")] as appropriate in this investigation. The collection of plants, microbes, and marine macro-organisms will be within the framework of the collection contract between the NCI and the NCI Contractor ("Contractor") which will collaborate with the appropriate agency in the [SCG or SCO]. The NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the [appropriate Source Country Institution ("SCI")] in [Source Country] as the agent appointed by the [SCG or SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The [SCG or SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of its plants, microbes and marine macro-organisms, subject to the conditions and stipulations of this agreement". [14]

(b) *Material Transfer Agreements (MTAs)* are common tools in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, microorganisms and cell cultures. They are used for exchange of materials in various contexts – exchanges between research institutions, and setting conditions for access to public germplasm collections or seed banks, and access by a researcher to *in situ* GRs, where the agreement will be between the research institution and the access provider. In most MTAs, a provider agrees to give identified physical material to a recipient, and the recipient agrees to restrict the uses that may be made of that material, and often of any improvements or derivatives. An example of the main clause of a standard MTA is contained in Sample Clause 8 as follows:

Sample Clause 8: Material Transfer Agreement

"*The provider is willing to transfer the material to recipient and to grant recipient a limited non-exclusive license to use the material under the terms and conditions specified in this Material Transfer Agreement (MTA). The recipient accepts the terms and conditions of this MTA by placing an order with the provider*". [15]

(c) *Licensing Agreements* set out certain permitted uses of materials or rights that the provider is entitled to grant, such as agreements to license the use of GRs as research tools, or to license the use of associated TK or other IP rights. Sample Clause 9 gives an example:

Sample Clause 9: Licensing Agreement

"*Harvard hereby grants to licensee and licensee accepts, subject to the terms and conditions hereof, in the territory and in the field:*
(a) a non-exclusive commercial license under patent rights, and
(b) a non-exclusive commercial license to use biological materials to make and have made, to use and have used, to sell and have sold the licensed products, and to practice the

[14] Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country Government (SCG)/Source Country Organization(s) (SCO), preamble

[15] Model Transfer Agreement (MTA) on Plant Genetic Resources for Food and Agriculture (PGRFA), recommended model for institutions participating in the "National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization" of the Czech Republic, Czech Gene Bank, Crop Research Institute (CRI) and providing PGR to users.Clause 3.1

licensed processes, for the life of the patent rights. Such licenses shall not include the right to grant sublicenses".[16]

(d) *Research Agreements or Research and Development Agreements* define various inputs to research or to research and development, including financial, material (including GRs) and intellectual contributions, specify various responsibilities in relation to the conduct of research and development of new products or processes, and set out how the monetary and non-monetary benefits from this research and development should be managed and shared. Some agreements are part of wider Co-operative Research and Development Agreements (CRADAs) as a common tool in biotechnology research. In essence, the parties agree to contribute various resources, such as existing IP, personnel, research facilities, in the collective pursuit of a shared research and development objective. For an example of a research agreement, see Sample Clause 10 and for a Co-operative Research and Development Agreement, see Sample Clause 11:

Sample Clause 10: Research Agreement

"Provider agrees to transfer to recipient's investigator named below the following Research Material: …
This Research Material will only be used for research purposes by recipient's investigator in his/her laboratory under suitable containment conditions. This Research Material will not be used for commercial purposes including for the avoidance of doubt for the production or sale of any products or for clinical use, for which a commercialization license may be required and recipient will not file patents on the Research Material of its uses or any material developed using the Research Material".[17]

Sample Clause 11: Co-operative Research and Development Agreement

"*The Hania plant (Withania Somnifera) material will be taken from natural habitat of Karimabad for R&D purposes for 5 years and commercial purposes for next 20 years with permission of the local government , if any. The local government will specify a 50 hectare land area where botanical garden for experimental work on Hania plant will be developed with technical support of NIH and financial support of Astra Zeneca. After expiration of 25 years, the botanical garden will be sole property of local government along with all its moveable and immoveable property*".[18]

(e) *Confidentiality or Non-Disclosure Agreements* requiring the recipient of information to keep it confidential, such as information concerning source of GRs, associated TK or know-how, which may be used in gaining access to GRs for evaluation purposes, developing a research collaboration, or as a condition of employment. Such agreements frequently limit the purposes for which such information can be used – depending on the circumstances, this may include limiting its use to evaluation, research, or non-commercial purposes, or limiting it to certain agreed purposes. See Sample Clause 12 on non-disclosure of confidential information including TK and Sample Clause 13 on confidentiality on information relating to patents.

[16] Non-exclusive License Agreement (sample) - Harvard College, United States of America. Section III

[17] Model Material Transfer Agreement (MTA) of the Korean Research Institute of Bioscience and Biotechnology, Clause 1 and 4

[18] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

Sample Clause 12: Non-disclosure Agreement

"*The confidential information including all intellectual property, such as traditional knowledge, practices etc shall remain the property of disclosing Party, even after the verification by recipient. The recipient agrees to hold all confidential Information in trust and confidence, both during and after the term of this agreement and agrees not to disclose to any person, firm or corporation, company subject specialist and / or use such confidential information in any manner*".[19]

Sample Clause 13: Confidentiality Agreements:

"*Company agrees not to disclose any portion of the Application(s) to any third party without prior written permission from PHS, shall use reasonable care to maintain the confidentiality of the Application(s) with at least the same degree of care as is exercised in respect of Company's own proprietary information, and shall disclose the Application(s) only to those of Company's employees who have a need to review the Application(s) for the purposes specified in paragraph 4 below*".[20]

Many actual agreements are, in fact, a combination of several of these categories or types of agreements, depending upon the individual circumstances of the collaboration.

IV. MAIN CONSIDERATION OF IP ISSUES

Once the preliminary steps and main overall considerations for access and equitable benefit sharing agreements have been taken into account, the main consideration of IP issues could be guided by the following overall IP issues (Part A), specific IP rights (B) and the exploitation of IP rights by licensing (Part C).

A. OVERALL IP ISSUES

The different elements of the overall IP issues are guided by the mutual understanding of the agreement developed by the parties in previous steps and by the goals set after assessment. In addition, they will depend on the type of agreement and the different factors affecting the agreement.

In general, there is a range of IP issues which are common to all negotiations of IP Clauses set out in this section. These IP aspects comprise general questions of development and management of IP (Cluster 1), specific practical aspects (Cluster 2), the need for a project planning related to IP management (Cluster 3), the sharing of benefits arising from the exploitation of IP rights (Cluster 4) and the need for specific IP terms and dispute settlement (Cluster 5).

Cluster 1: General IP questions

(a) What IP could result from the access to GRs?

(b) What conditions or restrictions should apply to seeking and obtaining IP rights?

[19] Non-disclosure agreement between National Innovation Fund (NIF) and recipient

[20] Confidentiality Agreement NIH, available at: http://www.ott.nih.gov/pdfs/cda.pdf

(c) How should those IP rights be owned, exercised, maintained and licensed?

(d) What approach to obtaining, holding and exercising rights best promotes a mutually beneficial outcome, and the equitable sharing of benefits from the permitted access?

It is crucial to consider in advance what IP is likely to result from the intended access. If access to GRs is intended for applied research, it is likely to have IP implications. This is especially so if research collaboration is aimed at developing a commercial product or process. Potential IP on research outcomes and commercialization activities could include a range of IP rights, depending on the direction taken in research and development: these could include patents, plant variety rights, trademarks, geographical indications, designs, trade secrets, and copyright.

Distinction between IP potentially covered and actually covered or excluded

The parties may therefore need to review the potential IP resulting from the permitted access, and in particular:

(a) What subject matter could potentially be covered by IP?
(b) What elements of this material should actually be covered by IP (for instance, new products created by the research)?
(c) What elements should be excluded (some material transfer agreements, for example, oblige the recipient not to seek IP rights on the transferred material, or require further negotiation and agreement at the stage when basic research begins to deliver outcomes)?

Cluster 2: Specific practical IP questions

These basic questions then lead to specific practical IP questions such as:

(a) *Right to application*: Who will decide whether to acquire IP rights on various categories of subject matter? What kind of consultation and further agreement may be necessary before IP rights are acquired and exercised?, if at all;
(b) *Ownership*: Who will have ownership of IP rights?
(c) *Licensing arrangements* that should apply to ensure access to new technologies;
(d) *Payment* for acquisition and maintenance of IP rights;
(e) *Enforcement*: Who will police and enforce IP rights in the market place?
(f) *Sublicensing*: Participation in decisions on sublicensing;
(g) *Performance standards*: Ownership or licensing implications if certain performance standards are not met (for example, if the party that gains access to the resources decides not to develop the resources, or takes too long to do so, then the party giving access may wish to reserve rights over intellectual property and any research outcomes);
(h) *Reporting and disclosure*: Obligations to report on any actions taken to take out IP rights, and obligations to disclose the source or conditions of access to GRs.

Additional aspects related to IP

It might be useful to consider additional aspects related to IP going beyond management of IP rights themselves:

- If the research activities are wholly academic in nature, and are not aimed at the development of new products or processes, it is nonetheless likely that the parties will

wish to create and publish articles and associated data, giving rise to copyright in those publications and related transfer or licensing issues.

- Privacy and confidentiality issues also may apply – a traditional community may make access conditional on non-disclosure of certain traditional knowledge, for instance, and a resource provider may require that the specific origin of a rare or endangered genetic resource be kept confidential.

- Academic research projects may wish to provide, or to use, genetic material that is already subject to third party IP protection. Appropriate warranties may need to be sought or given, for instance, a warranty that the provider or licensor holds all legal right, title and interests in and to those IP rights. Alternatively, the provider or licensor may assert that it does not extend any warranties that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights.

- IP rights are territorial in nature, which means that they can be owned or exercised discretely in various countries. So the decisions made on these questions can specify different arrangements for different territories. For example, the access provider could choose to retain IP rights in the country of origin, but might agree to the partner owning IP rights in other markets.

- An agreement might specify that licenses be automatically granted to third parties if the recipient fails to meet certain agreed performance criteria, such as making a new product available in developing countries at a preferential price.

For an example of a clause on publications and confidentiality, see Sample Clause 14:

Sample Clause 14: Additional confidentiality aspects

"*In all oral presentation or written publications concerning the Research Project, recipient will acknowledge provider's contribution of this Research material unless requested otherwise. To the extent permitted by law, recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of provider's written information about this Research Material that is stamped "confidential", except for information that was previously known to recipient or that is or becomes publicly available or which is disclosed to recipient without a confidentiality obligation. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if provider has given confidential information to recipient such public disclosure may be only after provider has had thirty (30) days to review the proposed disclosure*".[21]

Joint ownership of IP Rights

Joint ownership of IP rights is one legal option, and may be preferred as one way of ensuring that the provider retains a distinct stake in the outcomes resulting from the access.

On the other hand, joint ownership can lead to unexpected practical problems and limitations, and may not always be an appropriate benefit-sharing mechanism. For example, joint ownership does not necessarily create an entitlement to receive benefits from the other owner's exploitation of the common IP rights. In some jurisdictions, joint ownership of patent rights does not require one owner to share economic benefits with the other owner.

[21] Model Material Transfer Agreement (MTA) of the Korean Research Institute of Bioscience and Biotechnology, Clause 5

In cases of joint ownership, the provider and user of the resources should consider how the responsibilities flowing from co-ownership of IP rights will be apportioned, as ownership generally brings with it the costs and responsibilities of securing and maintaining rights, as well as enforcing them.

Cluster 3: Project planning for potential IP aspect

For a research relationship involving GRs, initial planning of the project should consider the likely outcomes of the collaboration and how IP rights in those outcomes should be handled. This should ensure that, right from the start, any IP rights and potential benefits associated with them can be properly managed. Progressive decisions on IP could be programmed to be taken at key points – for instance, an initial evaluation phase, a review of research proposals and assessment of specific research outcomes. Prospective partners should build into overall project planning of different IP issues such as:

(a) What are the possible IP outcomes that could arise from the proposed collaboration?

(b) How important is ownership of these IP rights to the collaborators? What about ownership of improvements and future developments?

(c) How will benefits be shared arising from the successful exploitation of any IP? Who will negotiate and agree the terms of any subsequent licensing arrangement?

(d) What applicable legislation must be taken into consideration when analyzing the above, including relevant international, regional or national laws or regulations, including, where applicable, sui generis legislation on the protection of TK and customary laws?

Cluster 4: Sharing of benefits arising of the exploitation of IP rights

The crafting of IP provisions in an access agreement can help create benefits resulting both directly and indirectly from the access to GRs, and can be integral to ensuring the benefits are shared effectively and equitably. Some benefits may arise directly from the successful creation and exploitation of IP rights, such as through royalties from licensing IP. But benefits can extend beyond simple monetary payments, or the ownership and licensing of IP[22].

Broad understanding of benefits

When the access provider is a government agency, a public institution or other authority (such as a national park authority), or a community organization, a broader conception of benefit-sharing may be more consistent with their interests, values and objectives. For such providers, benefits may be assessed in terms of local development, enhanced environmental management, biodiversity conservation, access to technologies in addition to those resulting from the access, transfer of technologies to developing countries, investment in local research and economic activities, and favorable or social marketing arrangements for agreed derivative products and processes.

The need to understand the partners' different value systems applies not just to assessing the values of contributions or inputs to the collaboration, it also applies to assessing the

[22] The Bonn Guidelines provide an illustrative list of diverse possible monetary and non-monetary benefits from access to genetic resources: this list is attached to these draft guidelines as Appendix I.

importance and value of prospective benefits. IP provisions of an agreement can be structured to support many of these broader goals, and for this reason, the full range of potential benefits should be reviewed and kept in mind when the specific IP provisions are negotiated.

An agreed approach to IP provisions may flow from a comprehensive assessment of the full range of potential benefits, and ways of apportioning and sharing them. There could be:

(a) Specific monetary benefits flowing from the exploitation of IP rights, which could include: license fees, in the event of a licensing of the IP rights to a third party or the development of, for instance, a fee-paying database; the sale price, in the event of an assignment or sale of the IP right to a third party; royalties, in the event of a successful commercialization of the IP rights, whether as a result of sale, licensing or joint venture; salaries, where provider country nationals are involved in the exploitation of the IP rights. Monetary benefits may vary between different sectors. See Sample Clause 15 below:

Sample Clause 15: Monetary benefit sharing[23]

"Purpose of the Product	Gross Exploitation Revenue received in one calendar year ($ Australian Dollars)	Threshold Payment (% of gross Exploitation Revenue)
Pharmaceutical, Nutraceutical or Agricultural	< 500 000	0
	500 000 – 5 000000	2.5
	> 5 000 000	5.0
Research	> 200 000	2.5
	or	
	< 100 000	0
	100 000 – 3 000 000	1.0
	> 3 000 000	3.0
Industrial, Chemical, Diagnostic or Other	> 200 000	1.5
	or	
	< 100 000	0
	100 000 – 3 000 000	1.0
	> 3 000 000	2.0"

(b) Specific non-monetary benefits flowing from the exploitation of IP rights, which could include: responsibility for filing, maintenance and enforcement of those IP rights; responsibility for the negotiation of any subsequent joint ventures, assignments and/or licensing agreements; capacity building, such as IP-related training and education. Sample Clauses 16 and 17 provide examples of different options:

Sample Clause 16: Non-monetary Benefit-sharing

[23] Model Access and Benefit Sharing (ABS) agreement between Australian Government and access party

"*Non-Monetary Benefits include:*
(a) investment in the capacity of the Queensland-based biotechnology industry;
(b) technology transfer to Queensland-based entities;
(c) creation of employment in Queensland;
(d) formation of collaborative agreements with Queensland-based entities;
(e) investment in Queensland-based entities;
(f) investment in research and development infrastructure in Queensland;
(g) conducting field and clinical trials in Queensland;
(h) undertaking commercial, production, processing or manufacture in Queensland;
(i) creation of alternative industries or crops in Queensland;
(j) improved knowledge of Queensland's biodiversity;
(k) improved knowledge of Queensland's natural environment; and
(l) lodgement of voucher specimens with the Queensland Museum or Queensland Herbarium".[24]

Sample Clause 17: Benefit-sharing
"*As mentioned earlier a separate chapter for Benefit Sharing has been included in the Contract. Following are the main points of this chapter regarding non-monetary benefit sharing:*
(1) The technical expertise of local people and farmer community will be prefered for development of 50 hectare Botanical Garden in Karimabad.
(2) The agricultural graduates and botanical experts of local area will be prefered for research work on Hania plant in the said Botanical Garden and they will be trained by experts of NIH and Astra Zeneca to develop their Negotiation capacity.
(3) Special IP training courses will be conducted for officials of Local Government to develop their capacities for royality and other arrangements.
(4) The technology should be transferred automatically to the Local Government after the expiration of 25 years of the contract".[25]

Cluster 5: Dispute settlement

Agreements have to anticipate the need for dispute settlement in the case of general disputes, and there should be an overall dispute settlement provision in the agreement, covering all aspects, not merely IP-related provisions.

The various mechanisms for resolving disputes, such as mediation, arbitration and litigation (including the jurisdiction that applies) should be considered and agreed upon, with a view to what is appropriate and effective (especially from the perspective of resource providers if they are confronted with limited capacity in terms of effective use of formal legal systems). Where access and benefit-sharing agreements are stipulated under specific national regimes, there may be mandatory requirements for dispute settlement. Alternative dispute settlement measures such as arbitration and mediation may take account of customary law interests and custodial responsibilities.

Shared understanding on specific terms to avoid disputes

[24] Model Biodiscovery Benefit-Sharing Agreement prepared by the State of Queensland, Australia to facilitate the development of the Queensland Biodiscovery Industry, Recital

[25] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

As a rule, the more the specific terms of an access agreement are based on a shared and full prior understanding of the nature of the access and benefit-sharing partnership and the intended use of the resources, the less is the likelihood of disputes relating to IP provisions.

Some IP issues may require specific dispute settlement: for instance, there may be provisions for arbitration on whether or not to proceed with IP protection for a particular innovation, whether or not a research outcome is derived from the accessed genetic resource and is therefore covered by the agreement, and when certain obligations may be triggered, such as an agreement to license IP to a third party in the event that the recipient does not meet certain performance standards. Different options for IP clauses on dispute settlement are provided by Sample Clauses 18 and 19:

Sample Clause 18: Dispute Settlement

"*A.17 ARBITRATION*
Applicable to agreements with private parties in India
A.17.1 Except as hereinbefore provided, any dispute arising out of this Agreement, the same shall be referred to the arbitration of two arbitrators, one to be appointed by each party to the dispute, and in case of difference of opinion between them to an umpire appointed by the said two arbitrators before entering on the reference, and the decision of such arbitrators or umpire, as the case may be, shall be final and binding on both parties. The venue of arbitration shall be at such place as may be fixed by such arbitrators or umpire and the arbitration proceedings shall take place under the Indian Arbitration Act, 1940.
A.17.2 Any legal appeal over the arbitrators' award arising out of or in any way connected with this agreement shall be deemed to have arisen in Thiruvananthapuram and only the courts in Kerala shall have the first jurisdiction to determine such matters."[26]

Sample Clause 19: Dispute Settlement

"Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be ... The language to be used in the mediation shall be ...

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within [60][90] days of the commencement of the mediation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. Alternatively, if, before the expiration of the said period of [60][90] days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of [three arbitrators] [a sole arbitrator]. The place of arbitration shall be ... The language to be used in the arbitral proceedings shall be ... The dispute, controversy or claim referred to arbitration shall be decided in accordance with the law of ...".[27]

[26] Know How Licensing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd, Coimbatore, India (the PARTY), dated November 10th, 1995

[27] See WIPO publication No. 446(E): WIPO Arbitration and Mediation Center, Recommended WIPO Contract Clauses and Submission Agreements

B. SPECIFIC IP RIGHTS AND ISSUES

Patents

A research project based on access to GRs may have as its clear intention the development of a product, process or technical solution that may be eligible for patent protection, and the subsequent licensing and commercial development of that patent. Alternatively, an academic collaboration may inadvertently or unexpectedly result in a patentable invention.

Is this a project which may result in the creation of a patentable invention?

Are the resources, and any related information, to be accessed for academic research purposes only, or will they be used in order to create, if possible, a product or a process that provides a new way of doing something, or offers a new technical solution to a known problem? Such a product, process or solution may be eligible for patent protection. Sample Clause 20 sets out different options:

Sample Clause 20: Different purposes of agreements

"*The recipient and the provider distinguish the following categories of use of MGRs:*
Category 1: Use for test, reference, bioassay, and control (covering only their use within the framework of the corresponding official (inter)national test-, bioassay and control protocols); use for training and research purposes;
Category 2: Commercial use. Commercial use of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval.
For category 1 uses:
The recipient will not claim ownership over the MGRs received, nor seek intellectual property rights over them or related information. If the recipient wishes to utilise or exploit such organisms commercially he will first inform the provider; when applicable, suitable and adequate recompense to those entitled to be rewarded, and the country of origin will be discussed in the spirit of the Convention on Biological Diversity.
The recipient will ensure that any individual or institution, to which the recipient makes samples of the MGRs available, is bound by the same provision.
For category 2 uses,
In order to ensure adequate benefit sharing with the country of origin and « names of those entitled to be rewarded », according to the principles of the Convention on Biological Diversity, the recipient will immediately inform the provider and the country where the MGRs were originally accessed, of the intended commercial use(s) of the MGRs and/or derived technology and/or related information. The terms upon which benefit sharing with the stakeholders takes effect are laid down in annex.
For all categories of uses, The recipient will mention the provider, the strain reference number and the country of origin in publication presenting scientific results and related information resulting from the use of the MGRs".[28]

General conditions of patentability and specific national and regional legislation

The rules for patent protection vary between different national and regional patent laws.

[28] MOSAICC, Septmeber 2009, *op.cit.*, page 20

An invention is generally required to be industrially applicable (or useful), new (or novel) and non-obvious (or involve an inventive step), and the invention has to be disclosed in the patent application according to certain standards.

There are differences between different laws on what technical subject matter can be protected, including in areas potentially relevant to inventions based on GRs. For instance, patent laws may exclude discoveries of materials or substances already existing in nature, scientific theories, plant or animal varieties, or essentially biological processes for the production of such plant and animal varieties, other than microbiological processes, as well as inventions that would contravene public order or morality if they were commercially exploited.

In a number of countries, the choice has been made to exclude certain categories of invention that can be directly relevant to the use of GRs.

Access and benefit-sharing agreements should acknowledge and respect the different scope of patentable subject matter that different national and regional systems provide for.

Should patent protection be obtained?

When drafting any contractual arrangement, the scope of the proposed use of the GRs and any related information should be clearly defined. This will help to clarify whether it is intended for IP rights to be obtained as a result of this use.

For instance, if the research is for specified academic purposes only, consideration could be given to both clearly defining the permitted research under the contract and also including a clause stating that no IP rights may be obtained over any GRs, progeny or derivatives transferred under the agreement, without the further agreement of the original provider of the material or related information. Such a clause could protect the original grantors of the resources and knowledge in the event of an inadvertent discovery of a potentially patentable invention by an academic researcher.

A clear understanding should be reached about seeking patent protection for inventions derived from the access and use of GRs, in the framework of a broader understanding of how equitable sharing of benefits should proceed.

The access provider may wish to restrict or otherwise place conditions on the use of patents on inventions that result from access to the resources.

Options regarding patents

A range of options have been used in practice, among others:

- *precluding any IP rights* on any developments based on the access to the resources, as a contractual condition of access (for instance, in MTAs granting access for evaluation purposes or pure research only);

- *providing for reporting and consultation* in relation to any developments based on the access to resources (so that the user of the resource needs to disclose any potentially patentable invention to the resource provider, when a decision is made as to whether to patent the invention and if so, how and in whose name, and subject to what conditions);

- *affirming the right of the user of the resource to seek patents on certain defined inventions*, but making this right subject to appropriate arrangements for sharing

benefits from the patents and from the use of the resource more generally (see also the option of co-ownership of any patents, discussed below); these may include obligations to share or pool research results, to provide open access for non-commercial use, research or breeding, to provide preferential access to developing countries or for humanitarian purposes, and to grant licenses in various circumstances consistent with the goals and interests of the resource provider;

- *reserving rights*, so that if the user of the resource elects not to proceed with research or development, or otherwise fails to generate the expected benefits from the resource, the resource provider might retain an entitlement to take control of new technologies developed under the mutual agreement;

- *providing for some research outcomes to be published defensively* and for the general public to access them – that is, published so as to ensure they are in the public domain, and preclude any other party from seeking IP rights on them, to preserve 'freedom to operate' for such technologies;

- *imposing other conditions concerning patents*, such as obliging the user of the resource to mention the source of the genetic resource or conditions of access in any patent application concerning inventions resulting from the access to the resource;

- *clarifying the scope of research* that the user of the resource may be entitled to undertake, and the implications for IP ownership, such as further development and improvement of the original invention, and applied research to enable industrial use of the invention.

These are only some of the options that could be chosen. Finding the right balance of interests that is both equitable and effective in achieving mutual benefit may involve exploring all these options.

If so, who may own such an invention?

Typically, co-ownership accrues with co-inventorship. Nonetheless, the parties can agree that any patent will be jointly owned by the partners, regardless of their contribution to the invention. Other more varied arrangements are also used: Patent rights on resultant inventions could be granted to the recipient, subject to further benefit-sharing, except in the territory of the provider, where patents could be jointly owned or owned by the provider.

Some further practical considerations may arise:

(a) *Employees' inventions*: In research and educational institutions, such as universities, the employer may be deemed to be the owner of an invention, when the invention is produced by an employee (such as a professional researcher or academic) within the scope of his or her employment. However, this rule may not apply to students involved in a research project on biological material, and they may have distinct rights to an invention, which should be taken into account in structuring IP provisions in an agreement;

(b) *Provider*: The grantor of access to the biological material and to any associated information may have retained certain contractual rights in relation to ownership of, development and licensing of any patent arising out of research carried out on the material or associated information;

(c) *Sponsoring organization*: A sponsoring private organization or government body may make certain demands on the ownership and use of any patents arising out of research collaboration, even if the researcher retains the basic entitlement to obtain patent rights.

Approaches to ownership of patents

Ownership can provide reassurance to the providers that they will retain a say over how the resources and any new technology derived from the GRs are developed, used and disseminated.

On the other hand, ownership of patents derived from access to GRs is unlikely in itself to generate tangible or sufficient benefits, in the absence of a strategy for managing actively a patent portfolio.

One practical consideration is that maintaining and exercising a patent portfolio, potentially in several countries, can be complex and entail significant investment. Normally, a patent owner bears the financial and administrative obligations to maintain and to enforce that patent, although contractual agreements can provide for other arrangements.

Joint ownership of patents is one possibility, but the implications of various ways of structuring ownership should be considered in advance.

In cases of joint ownership, the parties will need to consider how certain responsibilities are shared, such as making and maintaining a patent application, enforcing the patent in the event of infringement, and negotiating and agreeing the terms of any subsequent licensing arrangement - the organization that carries out research on genetic material may not be competent to develop a commercial product arising out of any successful research, so third parties may need to be involved. How these detailed arrangements are settled should be determined with reference to the overall arrangements set for access and benefit-sharing. For instance, some agreements require that any licensing of patents derived from the access to GRs should refer back to the original access and benefit-sharing agreement.

In some jurisdictions, if there is more than one owner of IP, then the consent of the other owner(s) must be obtained for an assignment or license; i.e. the agreement of all owners is required for effective development and exploitation of the patent. In other cases, unless the joint owners have agreed differently, each one is free to use the patented invention without being accountable to the others. It may be difficult to arrange three-way partnerships between potential licensees and third parties.

For this reason, it can be more practical for one co-owner to license or sell his or her interest in the patent to the other co-owner, subject to continuing access to the technology, payment or other conditions. In some cases, it may be more advantageous to concede ownership of any resulting patent in return for other benefits, such as a free license to use the patented product, process or technical solution, or broader benefits such as guarantees of access to technology for certain third parties, such as public authorities, developing country enterprises or non-commercial researchers.

Summary of issues

The following points summarize the patent-related issues that may need to be considered:

(a) *Patentable invention*: Will access to the GRs and related information result in the creation of a patentable invention? If not, and where the aim of the access is academic research only, this should be clearly stated in any contractual arrangement, and the

purposes of the access clarified accordingly. What is patentable can vary considerable between different countries. What the access provider and the user of resources believe should be patented will also vary, depending on their perspectives and interests.

(b) *Party obtaining patents*: What are the agreed arrangements concerning the obtaining of patents for any inventions resulting from the access? How do the access provider and user of the resources agree that patents should be obtained – are there requirements to report on inventions, to agree on specific patenting arrangements, or a general approach for all inventions resulting from the access?

(c) *Ownership of patents*: If so, who will be the owner(s) of the resulting patent? Will ownership be dependent upon such issues as the value of the contribution of GRs and TK, the level of scientific contribution and other contributions? Will the patent be jointly owned by the provider and user, regardless of their contribution to the invention? Or will the access provider retain ownership? Consideration may need to be given to the demands of a sponsoring private organization or government body on the ownership and use of any patents arising out of the collaboration.

(d) *Joint ownership*: In cases of joint ownership of a patent, how will responsibilities flowing from the co-ownership be apportioned? For instance, relating to filing, maintenance and enforcement. Where will the resources come from to carry out these activities?

(e) *Exploitation of the patent*: What is the most appropriate model for the exploitation of the patent and for the use and dissemination of the new technology developed – for instance, a license, assignment or joint venture? Who will negotiate and agree the terms of any subsequent arrangement to exploit the patent? The parties could negotiate licenses to commercialize the research outcomes, or a separate commercial or industrial partner could be brought in once the research outcomes were proven.

(f) *Sharing of benefits*: How, when and between whom will any monetary or non-monetary benefits arising from the commercial exploitation of the patent be apportioned? The provider of GRs and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the patent itself. Licensing royalties could be shared with the provider; alternatively, the provider may prefer to receive more immediate, short term benefits. In any event, consideration may need to be given to the establishment of specific structures or procedures to ensure that agreed benefits flow back to the provider; for instance, contract monitoring provisions and a benefit-sharing trust fund.

(g) *Confidentiality*: How will the parties maintain confidentiality? The principle of confidentiality plays a central role in the patent system and the leaking of any confidential information into the public domain can adversely affect the securing of future patents. It is therefore vitally important that confidentiality is maintained until adequate protection is in place. Consideration should also be given to agreeing terms related to publications, in order to ensure that prior publication does not destroy any future patent rights. For an example, see Sample Clause 21:

Sample Clause 21: Confidentiality Clause

"*The test results will be kept confidential by all parties, with any publication delayed until DTP/NCI has an opportunity to file a patent application in the United States of America on*

any active agents isolated. Such application will be made according to the terms stated in Article 6".[29]

(h) *IP warranties*: In carrying out the research, what use may be made of material or data covered by IP owned by others? Do warranties need to be sought, or given, relating to such IP? For an example to exclude such warranties, see Sample Clause 22:

Sample Clause 22: Potential IP of third parties

"*Use of the material may be subject to intellectual property rights. No express or implied licenses or other rights are provided herein to the recipient under any patents, patent applications, trade secrets or other proprietary rights. In particular, no express or implied licenses or other rights are provided to use the material or any related patents for commercial use*".[30]

Trademarks and geographical indications

The following issues relating to trademarks and geographical indications may be considered:

(a) Will access to GRs and related information result in the creation of goods or services, which could be identified by a distinctive sign linking the goods or services back to the provider of GRs? For instance, a word in a local dialect describing the resources in question, or a particular tribal symbol. See Sample Clause 23:

Sample Clause 23: Trademark protection

"*The medicine will be given a special commercial name "Astra-Hania" or "Hanio-Zeneca" and trade mark registration will be applied in Pakistan, UK and other target countries/regions at the end of the 2nd year of Contract*".[31]

(b) If so, does permission need to be sought to use such a word or symbol and, if so, from whom and on what mutually agreed terms? What limitations on the use, for instance to reflect cultural concerns, should be imposed?

(c) Who would own such a trademark? Who would be responsible for the cost of development, registration and upkeep of a trademark, including payment of renewal fees and enforcement?

(d) What would be the most appropriate commercial model for the exploitation of the trademark? It is common practice for trademark owners to license third parties, who operate in different countries, to use their trademarks in those countries. Could the trademark be assigned?

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[29] Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country Government (SCG)/Source Country Organization(s) (SCO), Clause A.2

[30] Model Transfer Agreement (MTA): Terms and Conditions of limited non-exclusive license model agreement to use genetic material of the Culture Collection of Dairy Microorganisms (CCDM) of the Czech Republic, Crop Research Institute (CRI), Clause 7

[31] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan).

(e) How would any benefits arising from the ownership, use and licensing of the trademark be apportioned? The provider of GRs and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the trademark itself.

(f) Are the GRs associated with a geographical indication? For example, are the resources linked with a traditional product that is distinctive of the geographical location where the resources are found? Are the GRs to be used for a product that has a quality, reputation or other characteristic that is essentially attributable to its geographical origin? What arrangements should be made to respect existing geographical indications, or to seek appropriate protection for geographical indications?

Copyright

Copyright may arise when information about GRs is recorded, and when accounts of TK are written down or otherwise recorded. Agreement at the time of access on ownership and use of this copyright is recommended. The following copyright-related issues may be considered:

(a) Will access to GRs and related information result in the creation of original materials that may be eligible for copyright protection, such as texts, technical drawings or databases? If TK associated with GRs is recorded, in an article or book, for instance, how will rights and benefits associated with that record be allocated? Particular consideration may need to be given regarding the IP rights in databases. The structure of a database may have IP protection in its own right, without prejudice to any copyright in the information contained in the database.

(b) Who will own the copyright in works that contain TK associated with GRs? In many research institutions, such as universities, the employer, and not the employee/author, is deemed to be the author of a work prepared by an employee within the scope of his or her employment. However, an access agreement may pre-emptively assign ownership of the copyright to the provider of the TK.

(c) In cases of joint authorship, how will responsibilities flowing from co-ownership of copyright be apportioned? Can copyrighted material produced from the collaboration be assigned or otherwise licensed to third parties? If so, on what terms? Consideration may need to be given to entering into a partnership agreement over the management of the joint rights.

(d) Where, and in what format, will the works be published? As a condition of publication, an author may be obliged to sign a Copyright Transfer Agreement, transferring ownership of the copyright to the publishing house. This is standard practice in serials and journals publishing and is designed to ensure maximum international protection against infringement, libel or plagiarism. This will not affect the author's moral rights.

(e) How will monetary and non-monetary benefits arising out of publication of copyright works be shared? The provider of GRs and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the copyright itself.

(f) What use may be made of material or data covered by third party IP? Do warranties need to be sought or given relating to third party IP?

Plant Variety Rights[32]

Plant varieties represent an important form of plant genetic resource[33]. They are relevant to access and benefit-sharing in at least two possible ways:

- the GRs that are accessed may be plant varieties; and
- because access to GRs may provide genetic inputs to plant breeding that creates new plant varieties.

In both cases, there are potential IP questions that should be considered before agreement is reached on the terms of access and benefit-sharing.

The following specific issues concerning plant variety rights may need to be agreed depending on the nature of access to GRs and their intended use:

(a) Will access to GRs and related information result in the development of a new plant variety(ies), through breeding or other research activities?

(b) What IP protection may be available for this new variet(y)(ies)? This differs according to the approach taken in national laws. Generally, some form of *sui generis* plant variety right is available. Some countries provide for patent protection of new plant varieties, in addition to plant variety rights or as an alternative.

(c) In what circumstances is it agreed that IP protection should be obtained for new plant varieties resulting from the access to GRs?

(d) Who will own the rights for any new plant variety, and how will this differ according to different territories? Will ownership be dependent solely upon contribution to plant breeding? Or will the IP be jointly owned by the provider and user, regardless of their contribution to the breeding of the new variety? In cases of joint ownership, how will responsibilities for management and enforcement be apportioned and funded?

(e) How may the plant variety right be commercially exploited, in what territories, and by whom? What forms of licensing the right are agreed as a condition of the original access?

(f) How may any benefits arising from such commercial exploitation be apportioned? As for other areas of IP derived from GRs, the provider of GRs and any related information

[32] IP protection has been developed specifically for new plant varieties. Different national systems provide protection through distinct, sui generis rights (termed 'plant breeder's rights' or 'plant variety rights'), patents on plant varieties, or both. Sui generis plant variety protection is available in many countries. The International Union for the Protection of New Varieties of Plants (UPOV), through the UPOV Convention, provides the only internationally harmonized system of plant variety protection in place. It comprises currently 68 member States. The UPOV Convention offers protection to the breeder of a new plant variety, in the form of a "breeder's right", if the variety satisfies the conditions set out in the UPOV Convention. In particular, the variety must be new, distinct, uniform and stable and must be designated by an appropriate denomination. When contractual arrangements for access to genetic resources relate to territories covered by the UPOV Convention, they should take account of the implications of the UPOV Convention for access to genetic resources, prior informed consent, and benefit-sharing, with regard to the "breeder's exemption", subsistence farmers and farm-saved seed. *These matters are explained in the "Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the CBD," available at: http://www.upov.int/en/news/2003/pdf/cbd_response_oct232003.pdf

[33] For details on the nature of plant varieties, see http://www.upov.int/en/about/upov_system.htm#what_is_a_pv

may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the IP right itself.

Trade Secrets

The following issues may arise in relation to confidential or undisclosed information:

(a) Will access to GRs and related information result in access to confidential information that may require careful handling and appropriate protection?

(b) If so, then as a matter of priority, the provider and user of the information should contemplate entering into a confidentiality agreement, to protect such information. Such an agreement could include the following terms:

(i) a description of the *information covered* by the agreement;
(ii) the *nature of the protection* required;
(iii) the *scope of the permitted disclosure* (who is authorized to get access to the information, including the need to put in place confidentiality obligations that cover the relevant employees or contractors of the institution receiving the confidential information);
(iv) the *scope of permitted use* (for technical or commercial evaluation; for non-commercial research; or for the development of a particular commercial product);
(v) *ownership and management of any further IP rights* that are created as a result of access to the confidential information, such as in the evaluation or testing process;
(vi) *time limitations* on the permitted use of the confidential information; and
(vii) *monitoring and reporting* on the use of the confidential information.

C. EXPLOITATION OF IP RIGHTS: LICENSING

An IP right does not in itself provide an economic benefit to anyone. For instance, the grant of a patent does not, *per se*, mean that an invention has an economic value and will be commercially viable. Furthermore, commercialization of an IP right, such as a patent, can involve a considerable amount of commercial risk, which may not be acceptable to smaller companies and dedicated research institutions, such as universities.

Because of these considerations, many users of GRs choose not to commercialize IP rights themselves, but elect between different options to manage those rights so as to get the commercial benefits of their research. Options include licensing, assignment and joint ventures.

Licensing Agreements[34]

Licensing agreements are a particularly common way to exploit IP rights related to GRs and related information, including TK. In the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access, and in which the equitable distribution of derived benefits is guaranteed.

[34] A license agreement is an agreement to permit an inventor to license an IP right, such as a patent or trademark, to others to develop and use commercially, whilst retaining ownership and control of the IP right itself and gaining benefits, such as financial royalties from the commercial development and use.

Checklist of licensing issues

Many providers and users of GRs may elect not to address the specific detail of exploitation of IP rights until an IP right has been created, and its potential commercial viability and value has been assessed. However, as part of an IP audit, it may nonetheless be useful to consider the following licensing-related issues, within the context of applicable international, regional or national laws or regulations. Some of these issues may need to be left open at the initial stage, and settled in detail only when the nature and potential of the results of research and development derived from the GRs are better known:

(a) *Definitions and Scope*: What IP rights arising out of the collaboration may, or may not, be licensed? (For instance, the right to use a patented process to produce a specified product, but not the associated trademark) What would be the purpose of the license? What would be the permitted scope of the licensed use?

(b) *Ownership of the IP rights that are being licensed*: Who retains ownership? In the case of joint ownership, who is entitled to grant licenses, under what conditions? See Sample Clause 24 as an example:

Sample Clause 24: Ownership of IP rights

"*Subject to Section 4 (License) it is understood that the AAFC Inbred Line(s) belong to Agriculture and Agri-Food Canada and that all intellectual property rights related to the AAFC Inbred Line(s) are vested and shall continue to be vested in Agriculture and Agri-Food Canada*". [35]

(c) *Grant of licensed rights.* The license needs to set out the exact rights that are (and are not) being granted. For instance, the right to use a patented process to produce a specified product, but not the associated trade mark. The use could be limited to research, or non-commercial, purposes;

(d) Type of license: What kind of license may be granted? Sole, exclusive or non-exclusive? The kind of license granted will influence the scale of royalties, or other payments made by the licensee. In which territory(ies) will the license apply? Can a sub-license be granted so that a third party may also use the IP rights in question? If so, to who, and on what terms or conditions? Will the licensor retain the right to use the covered invention? Is the license required to be registered with appropriate national authorities? If so, by who?.

The kind of license granted will influence the scale of royalties, or other payments, made by the licensee.

For an example, see Sample Clause 25:

Sample Clause 25: Scope and Type of License

"*Harvard hereby grants to Licensee and Licensee accepts, subject to the terms and conditions hereof, in the Territory and in the Field:*
(a) an exclusive commercial license under patent rights, and

[35] Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company, Clause 1

(b) a license to use biological materials […]".[36]

(e) *Territory.* In which territory(ies) does the license apply?

(f) *Sub-licenses.* Can a sub-license be granted so that a third party may also use the IP rights in question? If so, to who? On what terms or conditions?

(g) *Diligence and Milestones*. Where possible, certain defined points or milestones should be identified. If a licensee gains an exclusive license, subject to royalty payments on profits, and then does not use the technology for several years, then some of the value of the IP is effectively lost to the licensor. So, licenses will often include obligations on the licensee to develop and apply the licensed technology within a certain time scale. An obligation to use best efforts as contained in Sample Clause 26 would be one option:

Sample Clause 26: Best Efforts to Sell

"*The Company shall use its best efforts to sell the Licensed Product(s) to the end-users and sub-licensees. This obligation includes the twin duties of filling demand and creating demand for the Licensed Product(s). Nothing in the License Agreement authorizes the "shelving", deferral of, or otherwise enfeebled sales efforts or other activities which neither create demand nor fill demand for the Licensed Products, and any such activities are a material breach of the License Agreement*".[37]

(h) *Payments and Pricing*. There are many potential models for payment. It is always difficult to establish a value for IP, especially where it relates to unproven technology that will require a licensee to take a considerable commercial risk. Many licensing agreements consist of a mixture of lump sum payments and royalties, based on the extent of use of the technology. The need to monitor the use of the invention and to ensure that royalties are paid, as well as checking on diligence and milestone obligations, can lead to requirements for record-keeping, access to accounts etc. The approach taken to agreeing payments and pricing should be realistic, reflecting possible regulatory delays (especially in the biotechnology industry), and the fact that returns to the licensee can take many years to realize. Providers of GRs and related information may prefer to receive more certain up-front payments, rather than longer-term less certain returns.

(i) *Benefit sharing*: How will benefits flowing from the exploitation of the IP right be apportioned?

(j) *Confidentiality*. There may be a distinct confidentiality agreement, or obligations as to secrecy may be incorporated into the license agreement itself;

(k) *Copyright*. The license may set out the copyright provisions covering any manuals or other documentation received, and used, as part of the licensing package;

(l) *Ownership of improvements, grant-back rights and assign-back rights*: Who will own IP rights relating to improvements and adaptations to the licensed technology, whether arising from the licensed use of the technology or made by the licensor to the original

[36] Non-exclusive License Agreement (sample) - Harvard College, United States of America, Article III, 3.1(a)

[37] Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company, Clause 4.1

technology? A 'grant-back' clause may give access to a licensor to improvements made by a licensee. However, an exclusive 'grant-back' clause may be viewed under national law as anti-competitive commercial behavior. An assign-back clause would entitle the licensor to ownership in patents on any improvements. An example of a grant-back license to the licensor for improvement on the technology is contained in Sample Clause 27:

Sample Clause 27: Grant-back license:

"Recipient will give provider a non-exclusive, royalty-free license under any inventions it may patent that derive from the transferred material or improvements or derivatives thereof".[38]

(m) *Cross-licenses*. Under a cross-license, A grants B a license to use A's IP, and B grants A a license to use B's IP.

(n) *Required Performance*. A licensor (especially when granting an exclusive license) may wish to set specific performance targets in order to ensure a certain level of performance from the license agreement; for instance, minimum sales levels. A licensor may be expected to provide the licensee with assistance to exploit the IP effectively (such as training and technical support and advice). The licensee might need to submit an exploitation plan and report on business;

(o) *Publication of Research*. Terms related to publications may monitor developments in the technology and the licensed activities, and ensure that prior publications do not destroy any future patent rights. It is recommended to discuss and agree on whether the inventors have the right to publish their research and, if so, when;

(p) *Maintaining and enforcing IP rights*. Consideration will need to be given as to who may be responsible for ensuring that renewal fees are paid, and the respective roles of the parties in relation to enforcing the licensed IP rights. The licensor and licensee will need to agree who is responsible for ensuring that patent renewal fees are paid, and their respective roles in relation to enforcing the licensed IP rights. See Sample Clause 28:

Sample Clause 28: IP enforcement

"*Licensee shall have the right to prosecute in its own name and at its own expense any infringement of such patent, so long as such license is exclusive at the time of the commencement of such action*".[39]

(q) *Duration of license; Termination; Dispute resolution; and Choice of law*. A license will typically include provisions addressing all of these points.

(r) *Other issues*: These may include a guarantee clause (with provisions on liability and validity of authorizations, including prior informed consent under applicable law), provisions concerning challenges to validity of the IP rights (noting that competition law may not permit this), provisions concerning termination of the agreement before maturity, and provisions for amendment of the terms of the agreement including cases of changed circumstances (force majeure).

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[38] Example Material Transfer Agreement, in: Barton/Siebeck, *op.cit.*, page 21

[39] Exclusive License Agreement (sample) - Harvard College, United States of America. Section VIII 8.1

V. MODEL IP CONTRACTUAL CLAUSES

Once answers have been established to the questions raised by the IP assessment, and negotiations have been carried out to reach mutually agreed terms of access and benefit-sharing, appropriate contractual terms and conditions reflecting these negotiations can be drafted. The IP aspects of these negotiations can be included either as part of a wider benefit-sharing package or as stand-alone IP clauses.

Examples of actual and model IP clauses in contracts and licenses concerning IP, access to GRs and benefit-sharing can be found in the WIPO Contracts Database at: http://www.wipo.int/tk/en/databases/contracts/index.html. The information contained in the WIPO Contracts Database should be viewed as a general starting point, to be interpreted according to the individual circumstances of a particular collaboration.

VI. SECTORAL APPROACHES

IP clauses in agreements on access to GRs and equitable benefit-sharing should take into account the realities of different sectoral activities, in particular distinguishing between commercial and non-commercial use of GRs. Even if GRs are used in a wide range of different sectors and subsectors, a few main sectors can be identified, as well as their different circumstances, needs and purposes of their activities.

The most relevant sectors for IP and access and benefit-sharing seem to be: pharmaceuticals and biotech, food and agriculture, non-commercial research, as well as ex situ conservation. These sectors have been identified by a meeting of a Group of Legal and Technical Experts on Concepts, Terms, Working definitions and Sectoral approaches, which took place in Windhoek, Namibia in December 2008, mandated by the Conference of Parties of the CBD.[40]

It is worth noting that a wide range of national and international voluntary codes of conduct and best practices have been developed in different sectors using GRs, including by the FAO, the biotech industry or pharmaceutical companies, as well as the research community, botanical gardens, microbial collections[41].

The present draft guidelines apply to all different sectors. However, some brief considerations of sectoral approaches follow, based on the Report of the aforementioned meeting:

A. PHARMACEUTICALS AND BIOTECH[42]

The pharmaceuticals and biotechnology sector uses mainly GRs of plants, animals and microbes, accessed through material transfer agreements and collaboration agreements. The benefits are both monetary (up-front payments for samples, milestone payments, royalty payments) and non-monetary (technology transfer, scientific collaboration, training including student exchange and scholarships, and information exchange such as sharing of research results).

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[40] See Report of the Meeting of the Group of Legal and Technical Experts on Concepts, terms working definitions and sectoral approaches, UNEP/CBD/WG-ABS/7/2, December 2008.

[41] Document UNEP/CBD/WG-ABS/7/2 includes an Appendix with Examples of access and benefit-sharing standards and code of conduct from the non-commercial sector and the Pharmaceutical and Biotech Sector.

[42] See UNEP/CBD/WG-ABS/7/2

In general, activities in this sector are conditioned by a high risk and high investments, long research and development cycles and low probability of success. Therefore, it exists a critical need for legal certainty over a long period of cooperation and a need for reliability of material delivery over course of research.

Another significant characteristic is that the pharmaceutical industry acquires the majority of GRs from intermediaries such as culture collections. Only a few pharmaceutical companies directly access GRs from *in situ* conditions.

Therefore, agreements in the pharmaceuticals sector are mostly of commercial nature and therefore provide for clear IP protection on the possible results of research and development. IP protection may be sought for inventions of the recipient in the course of research and development. The commercialization may be subject to another agreement. Agreements mostly provide for some clauses in respect to reporting on the commercialization. For an example, see Sample Clauses 29 and 30.

Sample Clause 29: Patent protection for recipient's inventions

"*The [Transferee] shall not seek patents or plant variety protection rights in the Materials as such as they are listed in Article 2 (i.e., materials in the form they are transferred to the [Transferee]). The [Transferee] may apply for the grant of patents claiming inventions developed using samples of the transferred Materials, including inventions embodied in modified forms of the materials, or for the grant of plant variety protection claiming varieties developed using samples of the transferred Materials*". [43]

Sample Clause 30: Commercialization

"*If the Organisation proposes to undertake Commercialisation which is required pursuant to clause 8.2 to be authorised under a Commercialisation Plan, the Organisation may submit a draft Commercialisation Plan to the Department which must provide to the reasonable satisfaction of the Department, full details of:*
(i) all Commercialisation proposed to be authorised under the Commercialisation Plan;
(ii) all benefits (including Non-Monetary Benefits) for Queensland of the Commercialisation proposed to be authorised under the Commercialisation Plan; and
(iii) any aspect of the Commercialisation proposed to be authorised under the Commercialisation Plan which is proposed to occur outside of Queensland.[44]

B. FOOD AND AGRICULTURE[45]

The sector mainly uses crops, farm animals, forestry, fisheries, micro-organisms and insects related to food and agriculture, and their wild relatives primarily for breeding and selection, genetic modification, propagation and cultivation of the genetic resource in the form received, as well as conservation and other uses.

[43] Model Material Transfer Agreement (MTA) of the Biotechnology Industry Organization (BIO), Clause 4.3

[44] Uniform Biological Material Transfer Agreement, dated March 8, 1995 for the Transfer of Materials between Non-Profit Institutions and an Implementing Letter for the Transfer of Biological Material, Clause 8.3

[45] See UNEP/CBD/WG-ABS/7/2

The ITPGRFA provides facilitated access to plant GRs including detailed benefit-sharing and dispute settlement provisions. For access to animal and microbial GRs, no such international ABS mechanisms exist. In addition, many different and highly sophisticated exchange systems and material transfer agreements exist for micro-organisms for food and agriculture.

Other specific characteristics of the sector include:

- GRs are used for food production, as well as for the production of new GRs through recombination and breeding.
- Countries have become strongly interdependent for their food production.
- Input materials are generally available free of restrictions for further research and breeding
- For plants and micro-organisms large *ex situ* collections exist.
- The sector continuously reuses its own GRs for the generation of new products and needs access to a wide range of different GRs for the development of new products.

The Group of Legal and Technical Experts on Concepts, Terms, Working definitions and Sectoral approaches highlighted that the agricultural sector is unique due to a number of factors that explain why wide facilitated access is so useful and prevalent in the agricultural sector.

Some access and benefit-sharing agreements related to food and agriculture exclude the use of IPRs. See Sample Clause 31:

Sample Clause 31: Agricultural research

"The Recipient shall own the progeny or germplasm which are not essentially derived from the Material. The Recipient agrees that it: (…)

'(d) shall not seek intellectual property rights over the Material or related information which could act to the detriment of the continuing availability of the Material for agricultural research and breeding purposes'".[46]

Other agricultural research MTA provides for such possibility at a later stage. See Sample Clause 32:

Sample Clause 32: Agricultural Research including IP

10.7 The Commissioned Organization agrees that it will enter into equitable arrangements with the Collaborating Institution in relation to the following matters:

(a) the allocation of ownership of Intellectual Property in the Material between the Commissioned Organization and the Collaborating Institution in countries other than Australia and the Collaborating Country;

[46] A Material Transfer Agreement (Germplasm and Unregistered Lines) between the Department of Agriculture and Agri-Foods, Canada (AAFC) and several public breeding institutions and see Model Transfer Agreement (MTA) on Plant Genetic Resources for Food and Agriculture (PGRFA), recommended model for institutions participating in the "National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization" of the Czech Republic, Czech Gene Bank, Crop Research Institute (CRI) and providing PGR to users.

(b) the terms of any licenses between the Commissioned Organization and the Collaborating Institution to use or exploit the Intellectual Property referred to in clause 10.3 and paragraph (a);
(c) the terms of any licenses of other Intellectual Property owned or licensed by either the Commissioned Organization or the Collaborating Institution which are necessary for the utilization of the Material; and
(d) the allocation of costs relating to the application for and maintenance of the Intellectual Property rights between the Commissioned Organization and the Collaborating Institution.[47]

C. NON COMMERCIAL RESEARCH[48]

IP Clauses in access and benefit-sharing in non-commercial share the common element that the material transfer agreements and mutually agreed terms are primarily not aiming at commercial use and therefore mostly exclude the use of IPRs or provide the opportunity to renegotiate later commercial use and the exploitation of GRs by IPRs.

The sector is mainly characterized by the utilization of live and dead organisms and parts thereof for conservation, characterization and evaluation, production of naturally occurring compounds and DNA synthesis as part of a research process.

Standard mutually agreed terms and benefit-sharing arrangement terms (both monetary and non-monetary) are used in this sector.

Normally, no economic utilization of GRs or research results, and no product development, are expected and, therefore, intellectual property protection is not primarily sought. However, the agreements may include provisions concerning the change of intent from non-commercial to commercial research, eventually to seek new prior informed consent or to re-negotiate the material transfer agreement.

One of the specific characteristics identified by the experts is that there is an explicit agreement to a default benefit-sharing arrangement for unanticipated commercial benefits, or willingness to inform provider countries if any unanticipated potential commercial benefits are uncovered.

If no commercial use is intended, the agreement normally ends when the research is finished. In general, the material transfer or cooperation agreements are based on an interest in providing training and technical assistance. For an example, see Sample Clause 33:

Sample Clause 33: Change of interest

"*If the recipient, as the results of the field trials, has interest to develop the material in the commercial market, the recipient agrees to negotiate in good faith with INIA, prior to marketing of such products, the compensation to be paid by the recipient to INIA. Such compensation may include royalties on the gross sales value of such products derived from the material*".[49]

[47] Standard Conditions for Project Agreements between the Australian Centre for International Agricultural Research (ACIAR) and the Commissioned Organization

[48] See UNEP/CBD/WG-ABS/7/2.

[49] Material Transfer Agreement (MTA): Restricted License for non-profit purposes of the National Agricultural Research Institute (INIA Uruguay), Clause 10

D. EX SITU CONSERVATION[50]

Similar as the sector of non-commercial research, the sector of *ex situ* conservation, including botanical gardens and microbial resources centers, is primarily not aiming at commercial use and therefore mostly excludes the use of IPRs or provide the opportunity to renegotiate later commercial use and the exploitation of GRs by IPRs.

This sector uses mainly micro-organisms for collection, identification, preservation and distribution. The benefits are mainly non-monetary, such as sharing of microbes, conservation of microbes for sustainable use and consultation of treatment of microbes, such as cultivation and preservation. Microbes are mostly freely available for non-commercial research. Users have to negotiate mutually agreed terms if they want to use accessions commercially.

In addition, it was observed that ABS arrangements range from highly standardized forms of transactions to customized arrangements to meet the specific circumstances and interests of both provider and user. Use is also made of phased agreements, where, for instance, a research agreement is concluded for a first phase, and later on a second agreement might be concluded that will cover product development and commercialization. As access to resources for basic research normally precedes developing value chains, most requests for *in situ* access, therefore, are for research purposes.

However, IPRs could be part of future uses of the GRs provided. The sector has developed a wide range of code of conducts, guidelines and model material transfer agreements. For a typical clause making IP subject to a separate written agreement, see Sample Clause 34 and for non-monetary benefits of an *ex situ* conservation agreement, see Sample Clause 35:

Sample Clause 34: *Ex situ* conservation

"*BG Kew will not commercialise any Genetic Resources transferred under this Agreement. Without prejudice to the above, any Commercialisation to which RBG Kew and LARI may agree will be subject to a separate written agreement.*
"Commercialise" and "Commercialisation" shall include, but not be limited to, any of the following: sale, filing a patent application, obtaining, or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner; commencement of product development; conducting market research and seeking pre-market approval".[51]

Sample Clause 35: Non-monetary benefits in ex situ conservation

"*Benefits arising from the collection, study or conservation of Material transferred under this Agreement may include the following:*
- Accession of a representative, viable portion of the Material into the collections at the Seed Bank;
- Processing and viability testing of Material, its progeny or derivatives;
- Taxonomic identification of Material, its progeny or derivatives;
- Acknowledgement of LARI as the source of Material in research publications;
- Joint authorship of publications, as appropriate;

[50] See UNEP/CBD/WG-ABS/7/2

[51] Access and Benefit-Sharing Agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom

- Ensuring that the parties provide each other with copies of the results of all such scientific study, research and publications;
- Informing each other of any relevant opportunities for training and/or study by appropriate staff personnel at LARI or Kew;
- Encourage appropriate staff personnel at LARI or Kew take up any such opportunity for training and/or study". [52]

[Appendixes follow]

[52] Access and Benefit-Sharing Agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom

APPENDIX I

MONETARY AND NON-MONETARY BENEFITS

The Bonn Guidelines list the following potential benefits from access and benefit-sharing:

1. Monetary benefits may include, but not be limited to:

(a) Access fees/fee per sample collected or otherwise acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) Licence fees in case of commercialization;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

(a) Sharing of research and development results;
(b) Collaboration, cooperation and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the provider country;
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;
(e) Admittance to ex situ facilities of GRs and to databases;
(f) Transfer to the provider of GRs of knowledge and technology under fair and most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of GRs, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides GRs. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their GRs;
(h) Institutional capacity-building;
(i) Human and Material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Training related to GRs with the full participation of providing Parties, and where possible, in such Parties;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of GRs in provider countries;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;

(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

[Appendix II follows]

APPENDIX II

LIST OF ACTUAL AND MODEL CONTRACTUAL AGREEMENTS FOR ACCESS TO GRS AND BENEFIT-SHARING, REFERRED TO IN THE PRESENT DOCUMENT

1. Access and Benefit-Sharing Agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom
2. Confidentiality Agreement NIH
3. Exclusive License Agreement (sample) - Harvard College, United States of America
4. Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company
5. Know How Licensing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd, Coimbatore, India (the PARTY), dated November 10th, 1995
6. Material Transfer Agreement (Germplasm and Unregistered Lines) between the Department of Agriculture and Agri-Foods, Canada (AAFC)
7. Material Transfer Agreement: Restricted License for non-profit purposes of the National Agricultural Research Institute (INIA Uruguay)
8. Material Transfer Agreement, American Type Culture Collection (ATCC)
9. Memorandum of Understanding between [Source Country Organization] and the Developmental Therapeutics Program
10. Model Access and Benefit Sharing (ABS) agreement between Australian Government and access party
11. Model Biodiscovery Benefit-Sharing Agreement prepared by the State of Queensland, Australia to facilitate the development of the Queensland Biodiscovery Industry
12. Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country Government (SCG)/Source Country Organization(s) (SCO)
13. Model Material Transfer Agreement of Korean Research Institute of Bioscience and Biotechnology
14. Model Material Transfer Agreement of the Biotechnology Industry Organization (BIO)
15. Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations)
16. Model Material Transfer Agreement, MOSAICC 2009, the “Micro-Organisms Sustainable use and Access regulation International Code of Conduct”
17. Model project on “Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment” between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)
18. Model Transfer Agreement (MTA) on Plant Genetic Resources for Food and Agriculture (PGRFA), recommended model for institutions participating in the “National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization” of the Czech Republic, Czech Gene Bank, Crop Research Institute (CRI) and providing PGR to users
19. Model Transfer Agreement (MTA): Terms and Conditions of limited non-exclusive license model agreement to use genetic material of the Culture Collection of Dairy Microorganisms (CCDM) of the Czech Republic, Crop Research Institute (CRI)

20. National Science Foundation draft letter Uniform Biological Material Transfer Agreement, Non-profit to Non-profit, Quoted in Barton, John and Siebeck, Wolfgang. *Material transfer agreements in genetic resources exchange – the case of the International Agricultural Research Centres*. International Plant Genetic Resources Institute, May 1994
21. Non-disclosure agreement between National Innovation Fund (NIF) and recipient
22. Non-exclusive License Agreement (sample) - Harvard College, United States of America
23. Recommended WIPO Contract Clauses and Submission Agreements
24. Standard Conditions for Project Agreements between the Australian Centre for International Agricultural Research (ACIAR) and the Commissioned Organization
25. Uniform Biological Material Transfer Agreement, dated March 8, 1995 for the Transfer of Materials between Non-Profit Institutions and an Implementing Letter for the Transfer of Biological Material