A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements

THE ABS CAPACITY DEVELOPMENT INITIATIVE

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

This publication was prepared by the Traditional Knowledge Division of the World Intellectual Property Organization (WIPO) and the ABS Capacity Development Initiative. The lead authors are Maria Julia Oliva, Senior Coordinator for Policy and Technical Support, Union for Ethical BioTrade (UEBT), and Olivier Rukundo, Legal Expert on access and benefit-sharing and intellectual property, both consultants to WIPO and whose work was guided and coordinated by Daphne Zografos-Johnsson. Shakeel Bhatti guided and coordinated the later phases of the finalization of this publication. Support and comments were provided by Wend Wendland, Hartmut Meyer, Kathrin Heidbrink, Claudio Chiarolla, Lena Fey, Alice Manero and Rhona Rwangyezi. Special thanks are due to Pierre du Plessis, Rachel Wynberg and Tomme Young for peer-reviewing the first draft. The final draft was peer-reviewed by David Muls, Marco Aleman, Valérie Jouvin, Begoña Venero and Thomas Dillon, and edited by Toby Boyd.

About the multi-donor ABS Capacity Development Initiative

The ABS Capacity Development Initiative aims to contribute to poverty reduction, food security, technology transfer, social development including equity and rights, and biodiversity conservation through implementing in its entirety 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 and the third objective of the Convention on Biological Diversity, namely the fair and equitable sharing of benefits arising from the utilization of genetic resources. Established in 2006, the ABS Capacity Development Initiative is implemented by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, hosted by the Government of Germany, and co-funded by Norway, the Institut de la Francophonie pour le développement durable (IFDD) and the European Union (EU).

About the World Intellectual Property Organization

WIPO is the United Nations specialized agency for intellectual property issues. Its mission is to lead the development of a balanced and effective international intellectual property (IP) system that enables innovation and creativity for the benefit of all.

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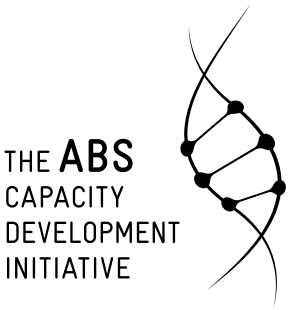

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Foreword

Genetic resources are subject to access and benefit-sharing regulations, in particular within the international legal and policy framework defined by the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, the International Treaty on Plant Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization and the Pandemic Influenza Preparedness Framework of the World Health Organization. Intellectual property issues are one of the elements of the broader framework on access and equitable benefit-sharing. The strategic management of intellectual property issues in an access and benefit-sharing agreement can influence the degree to which providers and users of genetic resources and associated traditional knowledge can achieve their goals and serve their mutual interests.

In May 2010, during the Sixteenth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC), the Secretariat of the World Intellectual Property Organization (WIPO) was invited to prepare and make available an updated version of the document entitled "Genetic Resources: Draft Intellectual Property Guidelines for Access and Benefit-sharing". The present guide, which has been prepared by WIPO in collaboration with the ABS Capacity Development Initiative, builds upon that document.

The guide, which is complementary and mutually supportive of the WIPO database of biodiversity-related access and benefit-sharing agreements, covers the conceptual and practical aspects of dealing with intellectual property in the context of access and benefit-sharing agreements. Its objective is to support providers and users of genetic resources and associated traditional knowledge when managing intellectual property issues in access and benefit-sharing agreements. It does so by explaining how intellectual property clauses may influence the approach and results of the utilization of genetic resources and associated traditional knowledge, providing an overview of the types of intellectual property-related issues that providers and users of genetic resources and associated traditional knowledge are likely to face when negotiating an agreement, and outlining the options available in managing those issues, thereby enhancing the information available to stakeholders.

Finally, the guide draws on a number of practical experiences across a range of economic sectors, including pharmaceuticals, industrial biotechnology, agriculture, cosmetics, and food and beverages, and describes issues that have arisen in practice in those sectors and the various approaches taken to resolving them.

It is my hope that this guide will support both providers and users of genetic resources and associated traditional knowledge in negotiating, developing and drafting intellectual property clauses in mutually agreed terms on access and benefit-sharing, facilitate understanding and promote practical solutions.

Francis GURRY
Director General

Figures and boxes

Acronyms

ABS	access and benefit-sharing
CBD	Convention on Biological Diversity
CGIAR	formerly, the Consultative Group for International Agricultural Research
IP	intellectual property
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
R&D	research and development
SMTA	Standard Material Transfer Agreement
WIPO	World Intellectual Property Organization

Executive summary

This guide describes how intellectual property (IP) issues arise in negotiations and agreements on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization or, as it is widely known, ABS. It has been produced by the World Intellectual Property Organization (WIPO) in cooperation with the ABS Capacity Development Initiative.

ABS is encouraged by several instruments of international law. The Convention on Biological Diversity (CBD) recognizes the sovereign rights of States over their natural resources and their authority to determine access to genetic resources in areas within their jurisdiction. The CBD establishes key principles for regulating ABS, including that conditions for access to or utilization of genetic resources and the sharing of any resulting benefits must be based on "mutually agreed terms". The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the WHO Pandemic Influenza Preparedness Framework are also essential references for negotiations and agreements on ABS.

IP considerations often arise in negotiations or agreements on ABS. For example, this may occur because the proposed utilization of genetic resources is expected to lead to innovations or new knowledge that might be subject to IP rights. Additionally, IP considerations may arise during negotiations on benefit-sharing. The Nagoya Protocol mentions the sharing of research and development (R&D) results, payment of royalties and joint ownership of IP rights as possible monetary and non-monetary benefits.

The objective of this guide is to support both providers and users of genetic resources in negotiating and drafting IP clauses in ABS agreements, by explaining how IP clauses may influence the approach and results of the utilization of genetic resources, and how benefits arising from such utilization are created and shared.

This guide is organized into four sections. Section 1 introduces some key terms and international instruments. Section 2 introduces different types of IP rights and explains how such rights may be relevant in the context of negotiating ABS agreements. Proposed R&D, for instance,

may result – either purposefully or unexpectedly – in the conception of a patentable invention. Mutually agreed terms may thus need to consider issues such as patent ownership, management, licensing and enforcement.

Section 3 focuses on IP management issues. It describes how IP rights may be exploited and managed as a way of advancing the broader purposes of ABS agreements. For example, parties may consider the different ways in which IP rights can be used and leveraged; whether to exclude others from manufacturing and distributing products that involve patented processes or products; licensing the IP rights for others to use in return for royalties; or selling the IP rights to realize a capital sum.

Section 4 considers the particularities of the interface between IP and ABS agreements in different industrial sectors engaged in the utilization of genetic resources. Sectors such as pharmaceuticals, agriculture and cosmetics approach research, development and commercialization activities, including in relation to genetic resources, in significantly different ways. This may have an impact on the strategic importance of IP protection, the types of IP rights and the way these rights are managed in ABS agreements. For instance, patent protection is often essential for the development or commercialization of industrial biotechnology processes and products. ABS agreements may thus need to focus on patent ownership and management when dealing with companies in this sector. In cosmetics and personal care, business strategies may be more focused on trade secrets, meaning that mutually agreed terms may require particularly stringent confidentiality clauses or parallel non-disclosure agreements.

By providing an overview of the types of IP-related issues that arise in mutually agreed terms, the options for managing these issues and related strategic considerations, this guide hopes to facilitate understanding and promote practical solutions for both providers and users. In this way, it aims to help promote fair and equitable benefit-sharing and the conservation and sustainable use of biodiversity.

1. Introduction

About this guide

This guide covers the main conceptual and practical aspects of dealing with intellectual property (IP) in the context of access to genetic resources and the fair and equitable sharing of benefits arising from their utilization – or, as it is widely known, ABS.

ABS is based on *prior informed consent* being granted by a provider of genetic resources to a user of such resources, and on negotiations between both parties to develop *mutually agreed terms*, in order to ensure the fair and equitable sharing of benefits arising from the use of the resources.

IP considerations often arise in negotiations or agreements on ABS. This may occur, for example, because the negotiations address access to and utilization of traditional knowledge associated with genetic resources, and access to that knowledge raises IP issues. Or, it may be expected at the time of the negotiations that R&D on the genetic resources may lead to innovations or new knowledge that might be subject to IP rights.

In this context, IP clauses in mutually agreed terms may influence the utilization of genetic resources, and how benefits arising from such utilization are created and shared. This includes the decision whether to seek and enforce IP rights at all, and, if so, under what conditions.

Target audience

This guide aims to serve both providers and users of genetic resources when negotiating, developing and drafting IP clauses in ABS agreements.

Providers of genetic resources may include government agencies, landowners, companies, academic institutions, ex-situ collections such as gene banks, and indigenous peoples and local communities. Providers must decide whether to grant access and, if so, what the conditions for such access should be.

Users of genetic resources may include research institutions, companies and individuals wishing to conduct research and development on such resources.

Establishing clear terms for the use of IP as part of mutually agreed terms is important for both providers and users of genetic resources. IP rights can protect both rights over genetic resources and rights over research and innovation results.

Scope

This guide provides general practical information for those who may be involved in negotiating IP clauses in ABS agreements. Drawing on practical experiences in a wide range of ABS scenarios, it describes issues that have arisen in practice and the various approaches taken to resolve them.

This guide focuses only on IP-related considerations that may arise in the negotiation of ABS agreements, but IP is only one possible issue among other practical and legal questions that may need to be addressed. The diversity of national laws, ways of utilizing genetic resources, types of actors, and the practical interests of providers and users means that a wide range of possible topics and choices may need to be considered when actual provisions are negotiated and drafted. These issues and choices may or may not involve IP. The guide focuses on IP issues related to genetic resources and does not address IP issues concerning traditional knowledge associated with those resources, except where associated traditional knowledge is expressly mentioned.

It is also important to note that this guide is not a standalone tool; rather, it complements WIPO's Collection of Biodiversity-related Access and Benefit-sharing Agreements, an online database of actual and model access and benefit-sharing agreements and related information, with particular emphasis on the IP aspects of such agreements. The Collection is available at: *www.wipo.int/tk/en/databases/contracts/*. It includes customized search engines allowing you to undertake structured or free-text searches, as well as browse the contracts. Many sample clauses referred to in this guide are taken from the Collection, and a wide range of additional clauses and contracts may be found within it. WIPO continuously updates the Collection, and readers who have their own sample contracts or clauses are invited to contribute by contacting WIPO via the Collection webpage. The current guide is thus an adjunct or reference resource that can be used by both providers and users when negotiating ABS agreements.

Structure

Beyond this introductory section, this guide is structured as follows:

- Section 2 briefly explains why IP rights may be sought in the context of mutually agreed terms, and what some of the considerations may be when negotiating and securing IP rights. It also provides an overview of the types of IP rights that may be relevant in the context of ABS agreements.

- Section 3 focuses on IP management issues that may need to be considered in the context of negotiating mutually agreed terms. It recognizes that IP rights may be exploited and managed in many different ways, from licensing the rights themselves to commercializing products based on components protected by IP rights.

- Section 4 looks at how genetic resources are utilized in selected industrial sectors, including pharmaceuticals, agriculture and cosmetics. It analyzes particular approaches to research and development and how IP protection may affect the negotiation of IP clauses in mutually agreed terms.

Disclaimer

This guide seeks to inform users and providers about IP issues that may arise in the negotiation of ABS agreements, and about possible approaches to address those issues. While it provides a range of examples of clauses and checklists to illustrate the issues and approaches discussed, it does not prescribe any one template or offer a set of predetermined choices. It is not intended to offer legal advice or advocate any particular policies or approaches.

Furthermore, this guide is not a substitute for legal advice either on general issues of contract law, or on more specific issues relating to IP in ABS agreements. It is not meant to teach how to negotiate contracts in general. It does not provide basic knowledge in areas such as general contract law, private international law or dispute resolution. While the

guide touches upon general IP law and ABS principles, it does not provide detailed information on these topics.[1]

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

None of the sample clauses listed in this guide is intended as a "model" or as "best practice". The sample clauses are provided for illustrative purposes only, and numerous other illustrative clauses and contracts may be consulted online in the WIPO Collection of Biodiversity-related Access and Benefit-sharing Agreements.

All reasonable precautions have been taken by the authors to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied.

Relevant international instruments

The guide takes into consideration several relevant international agreements and instruments.

Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD) entered into force on December 29, 1993. It has three main objectives: conservation of biological diversity; sustainable use of the components of biological diversity; and fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

[1] On drafting ABS agreements generally, see: T. Young and M. Tvedt (2016). *Introduction to Drafting Successful Access and Benefit-Sharing Agreements.* Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, Eschborn, Germany; available at: *www.abs-initiative.info/fileadmin/media/Knowledge_Center/Pulications/Introduction_to_Drafting_Successful_ABS_Agreements/Introduction_to_Drafting_Successful_ABS_contracts_-_ABS-I_FNI_-_201609.pdf;* K. Bavikatte (2014). *How (Not) to Negotiate Access and Benefit-Sharing Agreements.* Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, Eschborn, Germany; available at: *www.abs-initiative.info/fileadmin/media/Knowledge_Center/Pulications/ABS_AGreement/How_not_to_negotiate_Access_and_Benefit_Agreements_20140711.pdf;*
S. Heitmüller, H. Meyer, K. Bavikatte, M. Tvedt, V. Normand, P. du Plessis (2014). *The ABS Agreement: Key Elements and Commentary.* Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, Eschborn, Germany; available at: *www.abs-initiative.info/fileadmin/media/Events/2014/5-8_August_2014__Nadi__Fiji/The_ABS_Agreement_-_Key_Elements_and_Commentary.pdf*

The CBD recognizes that States have sovereign rights over their natural resources and hence the authority to determine conditions for access to genetic resources in areas within their jurisdiction. Article 15 of the CBD outlines a set of ABS principles. Among these are:

- Access to genetic resources must take place with the approval – or "prior informed consent" – of the country from which the resource is accessed.

- Conditions for access to or use of genetic resources, including how any resulting benefits would be shared, must be agreed: access and benefit-sharing must be based on "mutually agreed terms" to be negotiated with the country providing the resources (also in some countries delegated to an agency or community).

Furthermore, Article 8(j) of the CBD affirms the need for governments to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities". This provision further calls for the approval and involvement of the holders of such knowledge, innovations and practices, and encourages the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.

For more information on the CBD, see: *https://www.cbd.int*

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

Biodiversity in Costa Rica.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol)

The Nagoya Protocol was adopted on October 29, 2010 in Nagoya, Japan, and entered into force on October 12, 2014. It provides an international framework for implementing and advancing the third objective of the CBD. The Nagoya Protocol contains key obligations related to access to genetic resources, the fair and equitable sharing of benefits arising from their utilization, and compliance.

Furthermore, the Nagoya Protocol provides a new and innovative definition of the utilization of genetic resources. According to Article 2 of the Protocol, "'utilization of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the CBD".

For more information on the Nagoya Protocol, see: *https://www.cbd.int/abs*

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

ABS training for indigenous peoples and local communities in Guyana.

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

The ITPGRFA addresses the specifics of plant genetic resources for food and agriculture. It was negotiated under the auspices of the FAO Commission on Genetic Resources for Food and Agriculture, and entered into force on June 29, 2004. The Treaty establishes a multilateral system of access and benefit-sharing which aims to facilitate the exchange of seeds and other genetic material of a number of crops deemed significant for food security.[2] In this regard, the ITPGRFA constitutes a specialized international instrument on ABS that is consistent with and does not run counter to the objectives of the CBD and the Nagoya Protocol, as foreseen in Article 4.4 of the Nagoya Protocol. As a result, it is the ITPGRFA, rather than the Nagoya Protocol, that establishes the framework and requirements for access to and utilization of those plant genetic resources for food and agriculture covered by the multilateral system.

For more information on the ITPGRFA, see: *www.fao.org/plant-treaty*, and for more information on the multilateral system within the ITPGRFA, see: *www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/overview*

Terminology used in this guide

This section introduces some basic terms relevant to IP-related considerations in ABS agreements. The aim is to give readers a common understanding of these terms, but the explanations provided are not meant to be precise definitions. When negotiating mutually agreed terms, parties may and should agree their own definitions of key terms. The explanations below may, however, clarify some common topics and thus help parties in that process.

Intellectual property (IP)

IP refers to creations of the mind, such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce. IP rights aim to reward such creative human endeavor, thereby promoting innovation, economic growth and a higher quality of life. As is the case with other property rights, one of the aims of IP rights is to allow creators or owners of patents, trademarks or copyrighted works to benefit from

[2] Crops within the multilateral system are defined in Annex I of the ITPGRFA.

their own work or investment. However, not all creations of the mind can be subject to IP rights, and different types of IP rights have different criteria for protection, rights and limitations. Furthermore, although some international harmonization has been achieved, national laws on IP may vary greatly.

In negotiating IP-related provisions in ABS agreements, parties will normally need to specify the particular "intellectual property" to which the agreement applies, as well as the particular IP rights that may be involved.

For more information on the concept and rationale of intellectual property, see WIPO, *What is Intellectual Property?* available at: *www.wipo.int/edocs/pubdocs/en/intproperty/450/ wipo_pub_450.pdf.* See furthermore, the WIPOLex database: *www.wipo.int/wipolex/en/*

Access and benefit-sharing (ABS)

Access and benefit-sharing refers to the way in which genetic resources may be accessed and used, and how the benefits arising from such utilization are shared between the people or countries using the resources (users) and the people or countries that provide them (providers).

Genetic resources

Article 2 of the CBD defines genetic resources as "genetic material of actual or potential value". Genetic material, in turn, is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity". The term "genetic resources" thus encompasses material from any biological source, with the exception of humans, which contains genes or derived biochemical compounds that may be useful. The term "derivative" is defined in the Nagoya Protocol as a "naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity".

Additionally, the Nagoya Protocol states that benefits arising from the utilization of genetic resources, as well as their subsequent applications and commercialization, must be shared in a fair and equitable way.

Genetic resources as such are not creations of the mind and therefore cannot be protected as IP. However, a range of sectors use genetic resources for research and development, including, for example, the pharmaceutical, industrial biotechnology, agriculture, cosmetics, botanicals, and food and beverage sectors. Information, products and processes resulting from such research and development are clearly creations of the mind and thus the utilization of genetic resources may create IP that may be subject to IP protection.

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

Fungi in a German beech forest.

Traditional knowledge

Although there is no agreed international definition, traditional knowledge can be described as a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural and spiritual identity. It is understood as knowledge, know-how, skills, innovations and practices that are passed between generations in a traditional context, and that form part of the traditional lifestyle of indigenous peoples and local communities who act as their guardians or custodians.

In this context, the term “traditional” does not mean “old” or “antique”. Indeed, for the most part, traditional knowledge is neither ancient nor inert, but a vital, dynamic part of the lives of many communities. Rather, “traditional” qualifies a form of knowledge which has a traditional link with a community, meaning that it is developed, sustained and passed

on within a community, sometimes through specific customary systems of transmission. It is the relationship with the community that makes knowledge or expressions "traditional".

For more information, see WIPO's webpage on traditional knowledge at *www.wipo.int/tk* and WIPO (2015) *Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*; available at: *www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_933.pdf*

Traditional knowledge associated with genetic resources

Traditional knowledge that provides guidance and insights as to the properties and potential applications of genetic resources and their preservation, maintenance and use is referred to as "traditional knowledge associated with genetic resources" or "associated traditional knowledge". Interest in and understanding of genetic resources is often enhanced by its associated traditional knowledge. The CBD, though without defining such traditional knowledge, recognizes its value and role in achieving its objectives.

Photos: © Hartmut Meyer/ABS Capacity Development Initiative

Herders and farmers in Uganda and Germany breed animals adapted to their traditional needs and uses.

Prior informed consent (PIC)

In ABS, prior informed consent refers to the explicit authorization that may be generally required before access to genetic resources and/or associated traditional knowledge is granted. A decision whether or not to grant prior informed consent will depend on the relevant legislative, regulatory and institutional frameworks. This usually involves both a negotiation and an administrative process. Generally, users seeking to access and utilize genetic resources would submit an application to the authority designated by the provider country, after which the national authority would ensure that the application goes to the appropriate person, agency or community, which would then decide whether to give its consent for the access.

Mutually agreed terms (MAT)

"Mutually agreed terms" refers to an agreement reached between the providers and users of genetic resources regarding the conditions for access to and utilization of these resources, and how resulting benefits are to be shared.[3] In practice, depending on relevant laws and regulations, mutually agreed terms on access and benefit-sharing may be negotiated between the user and various actors (governments, agencies, communities and/or other persons or entities) and set out in different types of contracts and agreements.

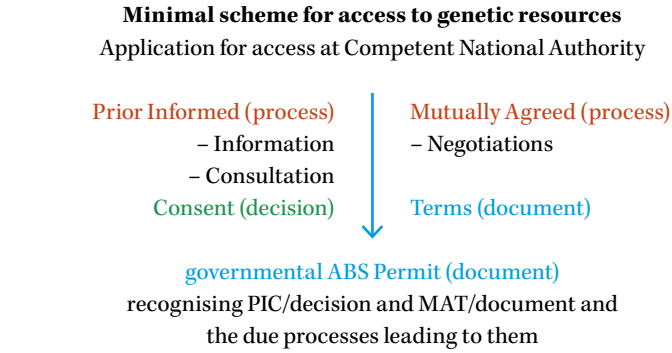
There are two common approaches to mutually agreed terms:

- In some countries, the negotiation of mutually agreed terms is directly delegated to the specific individual or community that is the provider of the particular genetic resources or traditional knowledge that are to be accessed and utilized. In these countries, mutually agreed terms are simply what the parties involved in an ABS transaction or partnership have agreed regarding access to those resources and sharing benefits from their utilization. These terms and conditions may be set out in material transfer, collaboration or benefit-sharing agreements, depending on the legal and regulatory requirements.

[3] See: CBD (2011). *Access and Benefit-Sharing Factsheet;* available at: *https://www.cbd.int/abs/infokit/revised/web/factsheet-abs-en.pdf*

- In other countries, the law may specify a particular governmental oversight/approval process, and may even identify particular terms or elements that must be included in the mutually agreed terms. In general, most of those countries also require the main negotiation of an agreement to be with the specific individual or community provider and may establish the specific types of instrument to be used or even provide a template.

Figure 1: A minimal scheme for access to genetic resources



2. IP rights in the context of mutually agreed terms on ABS

As noted above, different types of IP are protected by different IP rights, with different criteria for protection. Seeking and maintaining IP protection will generally entail cost and effort, but may bring considerable benefits to the right holders. In deciding whether to pursue protection, you therefore need to weigh that cost and effort against the potential benefits of such protection. You need to carefully consider what outputs resulting from intellectual activity can be protected by which IP rights, and what conditions have to be met to secure a given type of protection.

This section provides an overview of issues that can help guide this decision-making process. A brief overview of selected IP rights and their relevance to ABS is also provided.

Initial considerations

Deciding whether or not to acquire IP rights

A preliminary but very important consideration is to decide whether or not to acquire IP rights. This will depend on a number of factors, such as the nature and purpose of the project; the expected value of its outputs; the intended commercial or non-commercial goals; and the capacity to manage the acquired rights. Ultimately, this decision largely depends on whether the benefits of IP protection will outweigh the cost of obtaining it. For example, as will be further described later in Section 4, IP protection tends to have greater strategic and commercial value in sectors such as pharmaceuticals and industrial biotechnology, where R&D activities are costly and their results easy to replicate.

The decision to seek IP protection by a user may occur before, during or after the utilization of genetic resources. The use of genetic resources can lead to the conception of products or processes that IP law protects from unauthorized use by others. In some cases, the outcomes of the R&D process – i.e., the potential "subject matter" of IP protection – can be identified at an early stage. This would be the case, for example, for the development of an essential oil of a fragrant tree for use in perfumes. In other cases, such potential outcomes arise much later. For

example, a sample of soil may lead to the indentification of numerous microorganisms. Some of these may have interesting enzymes, but it could take years to identify how genetic modification can lead to interesting and useful enzymes.

Photos: © Hartmut Meyer/ABS Capacity Development Initiative

A regional training workshop on the negotiation of ABS agreements for CARICOM member states in Surinam.

Even when it is possible early on to identify creations of the mind that could be subject to IP protection, it is still necessary to decide whether the possible value of protection outweighs the cost of securing it. It is important to consider IP protection early on, especially for potential inventions, as it will not be possible to patent an invention that has already been disclosed. IP can create value and revenue in a number of ways: it can be sold or licensed; contributed as capital in a joint venture; offered to enter into strategic alliances; integrated with a current business; or used to create a new business. For instance, innovation-led companies that seek to develop new drugs, improve or adapt existing drugs or develop new pharmaceutical processes based on genetic resources tend to rely heavily on the patent system to ensure they recover the investments incurred in R&D. The choice of IP in this case has clear commercial implications that must be considered.

The checklist in Box 1 provides an indicative list of questions that may help in assessing these types of IP implications and guide decisions about whether or not to acquire IP rights and, if so, under what conditions.

Box 1: Checklist for deciding whether or not to acquire IP rights

- What benefits might the acquisition and use of IP rights give to the holders of the genetic resources?
- What kind of output (products or processes) is intended to result from R&D on genetic resources?
- Will the products or processes arising from the utilization of genetic resources have sufficient potential commercial value to justify the expense of seeking IP protection?
- Are these products and processes prone to rapid change and development? For example, synthetic biology, new genome engineering and next-generation sequencing are providing new insights on the potential use of genetic resources which could quickly make prior discoveries obsolete or commercially non-viable.
- Should there be any exclusion from the use of IP rights in the initial phase? Some material transfer agreements, for example, oblige the user not to seek IP rights on the transferred material, or require further negotiation and agreement at the stage when basic research begins to deliver commercial results.

Negotiating IP clauses and obtaining IP rights

At the stage of negotiation, parties should consider what possible results could arise from the utilization of genetic resources and associated traditional knowledge. Parties should also consider what IP implications may arise in the context of the mutually agreed terms, including as regards conclusion of the agreement, granting of access to the genetic resources and the carrying out of R&D.

Once these steps have been concluded, a user may decide to seek IP protection based on the ABS agreement and its applicable IP clauses.

Box 2 provides a checklist of examples of practical aspects to be considered during these various stages. These issues are explained in more detail in Section 3 of this guide.

Box 2: Checklist for negotiating and obtaining IP rights

- What conditions or restrictions should apply to those seeking and obtaining IP rights?
- Who will be responsible (including financially) for filing/registering the IP right and its prosecution?
- How should IP rights be owned, exercised, maintained and licensed?
- What approach to obtaining, holding and exercising rights best promotes a mutually beneficial outcome and the equitable sharing of benefits from the permitted access and utilization?
- Who will be responsible for enforcing IP rights once they have been obtained?
- In which countries should IP protection be sought?
- What IP legislation is in place in those countries?
- How early or late in the process should IP protection be applied for?
- What measures should be taken not to disclose the invention before seeking patent protection?

Types of IP rights that can arise in the utilization of genetic resources

As previously explained, IP may take a number of different forms, each with its own specific criteria for protection, rights and limitations. R&D arising from the use of genetic resources can result in a range of new ideas, products and processes, depending on the purpose and direction of these activities. Different R&D outcomes mean that different types of IP protection may be relevant.

This section provides an introduction to the different types of IP that may arise in the context of ABS agreements, including patents, trademarks, copyright and trade secrets. Each of these IP rights will be described considering five key questions:

(1) What is the IP right in question?
(2) What can be protected by it?
(3) What conditions must be met to obtain the right?
(4) What rights does it provide?
(5) How long does protection last?

In addition, each description will be followed by a discussion of how the IP right may be relevant to ABS agreements. Where appropriate, selected sample ABS clauses will be provided as well as a checklist of specific issues to be considered.

Patents

What is a patent?

A patent is an exclusive right granted for an invention, which is a product or a process that offers a new technical solution to a problem or provides a new way of doing something. To get a patent, technical information about the invention must be disclosed to the public in a patent application. This means that published patent documents become available as a potentially valuable source of technical and business information for inventors, enterprises and researchers. For more information on how to apply for a patent see the specialized materials available on the WIPO website.[4]

What can be protected by patents?

Patents may be granted for inventions in any field of technology, from an everyday kitchen utensil to a nanotechnology chip. An invention can be a product – such as a machine, a device, a formulation or a chemical compound – or a process, for example the process used to produce a specific chemical compound. Many products contain a number of inventions. For example, a laptop computer can involve hundreds of inventions, all working together.

Inventions resulting from the utilization of genetic resources may include, among others, new compositions, such as compositions of cosmetics, or new processes or methods of producing such compositions.

What conditions must be met to obtain patent protection?

A number of conditions must be met in order to obtain a patent. Rules governing patent protection vary between different national and regional regimes, so it is not possible to compile an exhaustive,

[4] See: *www.wipo.int/patents/en/index.html*

universally applicable list of requirements; but some of the most common requirements that have to be met to obtain patent protection include:[5]

- *Novelty:* The invention must show an element of novelty – some new characteristic which is not known within the body of existing knowledge in its technical field. This body of existing knowledge is called the "prior art".

- *Inventive step/non-obviousness:* The invention must involve an "inventive step" or be "non-obvious", meaning that it could not be obviously deduced by a person having ordinary skill in the relevant technical field.

- *Industrial application/utility:* The invention must be capable of industrial application, meaning that it must be capable of being used for an industrial or business purpose beyond being a mere theoretical phenomenon, or that it must be useful.

Furthermore, the subject matter of a patent must be accepted as "patentable" under the relevant law. For example, in some countries, plants are not patentable subject matter, even if they are newly developed, innovative and have a useful application. In order for the invention to comply with the requirements of novelty and inventive step, it is important not to disclose it before seeking patent protection. In addition, the invention must be disclosed in the patent application in a manner sufficiently clear and complete to enable it to be replicated by a person with an ordinary level of skill in the relevant technical field.

What rights does a patent provide?

A patent owner has the exclusive right to prevent others from commercially exploiting the patented invention for the period in which the invention is protected. In other words, patent protection means that if the invention is a product, it cannot be commercially made, used, offered for sale, distributed, imported or sold by others without the patent owner's consent. If the invention is a process, a third party not having the owner's consent cannot use the process or commercially exploit the product obtained directly by that process. Patent rights are subject to the principle of territoriality, that is, to the fact that patent protection needs to be sought distinctly in each relevant country or region.

[5] Some minimum standards in regard to patents for signatories of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are set out in Section 5 of that Agreement. See: https://*www.wto.org/english/docs_e/legal_e/27-trips.pdf*

How long does protection last?

Patent protection is granted for a limited period. This is generally 20 years from the filing date of the application, subject to payment of a maintenance fee and the patent not being revoked.

Box 3: Patents based on the utilization of genetic resources: the example of Salinosporamide

Salinispora tropica is a marine actinomycete bacteria found in marine sediments of the Bahamian coasts. In 1989, the Government of the Bahamas authorized the Scripps Institution of Oceanography of the University of California to collect and use sediment samples as part of a project looking for potential drug candidates. Researchers discovered the secondary metabolite Salinosporamide A produced by *Salinispora tropica*, which showed anti-cancer activity via proteasome inhibition. Patents were filed by the University of California over several medicinal applications of Salinosporamides. Other companies have since filed patents on the synthesis of Salinosporamide A and analogs. This case pre-dates the CBD and the Nagoya Protocol, but it is an example of how the utilization of genetic resources can lead to patent protection and the types of issues that may need to be considered in the context of mutually agreed terms.

How are patents relevant in ABS agreements?

A research project based on genetic resources may have as its intention the discovery of a patentable invention and the subsequent licensing of a patent and commercial development of that invention.[6] Even if there is no such intention, and particularly in the academic context, R&D may yet inadvertently or unexpectedly result in the conception of a patentable invention. Parties to ABS agreements can decide on specific conditions under which a patent may be sought in the eventuality that research on genetic resources leads to a patentable invention (see Box 4 for an example). Depending on their respective perspectives and interests, there may be differences in what a provider and user believe should be patented.

[6] This is, for example, usually the case in the field of biochemical research undertaken by private or public institutions that work in the area of medicine and the development of new active compounds.

The role of patents in ABS agreements may be different. In the first place, the function of patents to stimulate and disseminate innovation can contribute to there being more benefits that can be shared. Secondly, the Bonn Guidelines and Nagoya Protocol list joint ownership of patents and other relevant IP rights as one monetary benefit that can be shared through mutually agreed terms. Mutually agreed terms may also circumscribe the benefits to be created or shared, by limiting who may acquire and exercise patent rights.

Box 4: Sample clause on patents

"The recipient is free to file patent application(s) claiming inventions made by the recipient through the use of the material but agrees to notify the provider upon filing a patent application claiming modifications or method(s) of manufacture or use(s) of the material."

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; available at: *www.wipo.int/tk/en/databases/contracts/texts/ubmta.html*

In this context, the principle of confidentiality is often a key consideration in the negotiation of ABS agreements. R&D activities tend to be strategic in both commercial and non-commercial contexts. In negotiating mutually agreed terms, users of genetic resources are thus likely to seek protection in relation to information provided on R&D projects and results. For example, the leaking of confidential information may adversely affect future patent applications by making the invention part of the "prior art". In many jurisdictions a grace period is provided in relation to patents which allows for disclosure of the invention 6 to 12 months prior to filing without affecting the novelty. However, as the term of the grace period varies among jurisdictions, and it does even not exist at all in some, it is vital to keep relevant information confidential. As an example, the clause in Box 5 below restricts the publication of data or reports in order to ensure that prior publication does not affect the chances of securing patent protection later.

Box 5: Sample clause on confidentiality

"User and provider shall keep all data and summary reports confidential and shall not publish or authorize publication of data and summary reports with respect to a particular sample extract or sample compound, until the user has had a reasonable opportunity to file a patent application relating to a particular sample compound."

Furthermore, outcomes of R&D can be uncertain at the time of negotiating mutually agreed terms. Therefore, it may be difficult to anticipate or have answers to all patent-related issues early on in the process.

In some cases, a user may plan to invest a considerable amount of money and time in developing an invention based on the use of genetic resources. In such a case, acquiring a patent could be used as a means to acquire a pre-eminent market position to maximize returns on investment. Depending on the product or processes resulting from the use of genetic resources, a user may also opt not to exploit a patent themselves and may instead sell it or license the commercialization of the patented invention. In some cases, given the high-risk nature of bioprospecting and the low probability of finding and developing products or processes derived from the use of genetic resources, users may often decide to spread this risk through collaborative R&D. The provider of genetic resources may also opt to retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the patent itself. The provider may, for instance, request that licensing royalties be shared. Alternatively, the provider may prefer to receive more immediate, short-term benefits. In any event, the provider will likely need to consider specific structures or procedures to ensure that potential benefits arising from the exploitation of the patent flow back to them in one form or another.

In short, there are many ways to exploit a patent and, while it may not be possible to foresee potential R&D outcomes when mutually agreed terms are negotiated, the parties should at least try to ensure that they consider all relevant issues and possibilities.

Box 6 provides an indicative checklist of patent-related issues that may be considered by both users and providers at different stages of negotiating and concluding ABS agreements. Some of these issues may not apply or be relevant in all situations, but they are useful to keep in mind.

Box 6: Checklist of patent-related issues to consider in ABS negotiations

Patentability of R&D results

- Can the results of the utilization of genetic resources and related information be subject to patent protection?

Party obtaining patents

- What is the agreement between the user and provider as to how patents may be obtained? Is there a general approach for all inventions resulting from the utilization? Are there requirements to report on inventions or to agree on specific patenting arrangements?

Jurisdictions for patent protection

- In view of key markets, strategic manufacturing locations or other considerations, in which countries might it make sense to obtain patents?

Ownership of patents

- Who will be the owner(s) of the resulting patent(s)?
- Will ownership depend on such issues as the value of the contribution of genetic resources and traditional knowledge, the level of scientific contribution or other factors?
- 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 regarding the ownership and use of any patents arising out of the collaboration.

- If the provider is to retain ownership of any patents, will this be on condition that they grant the user a license?
- In cases of joint ownership, how will responsibilities flowing from the co-ownership be apportioned? Who will be responsible for filing, maintaining and enforcing the patent, and where will the resources come from to carry out these activities?

Exploitation of patents

- 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? For example, 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 are proven and/or the patent granted.
- Should no-cost licenses or other preferential terms be granted to entities in the provider country or other partners?

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?
- Which benefit-sharing mechanisms might apply in this case?

Confidentiality

- What elements should be kept confidential to ensure that disclosure does not jeopardize the chances of obtaining patent protection?

Photos: © Hartmut Meyer/ABS Capacity Development Initiative

Candles containing a mosquito-repellent extract from *Lippia javanica*. Traditionally, *Lippia* material is burnt in houses to repel mosquitoes. The South African Centre for Scientific and Industrial Research holds a national patent on the use of *Lippia* extracts and chemical substances. Under a license agreement with a South African company, *Lippia* bushes are grown and extracted and candles are produced in the local community, providing jobs and income opportunities. Through an ABS agreement, additional benefits are shared with traditional healers.

Trademarks

What is a trademark?

A trademark is a sign capable of distinguishing the goods or services of one enterprise used in the course of trade from those of other enterprises.

What can be protected as trademarks

A word or a combination of words, letters, and numerals can constitute a trademark. Trademarks may also consist of drawings, symbols, three-dimensional features such as the shape and packaging of goods, non-visible signs such as sounds or fragrances, or color shades used as distinguishing features – the possibilities are almost endless.

What conditions have to be met to obtain trademark protection?

A sign is protected by its registration as a trademark in the relevant territory or, in some countries, through its use in the marketplace. Though national laws vary from one country to another, distinctiveness is the key criterion.

What rights does trademark registration provide?

A trademark registration will confer an exclusive right to use the registered trademark in respect of the goods and/or services for which protection has been obtained. This implies that the trademark can be exclusively used by its owner, or licensed to another party. Registration provides legal certainty and reinforces the position of the right holder, for example in case of litigation.

How long does the protection last?

The duration of trademark registration can vary, but is usually 10 years. It can be renewed indefinitely, provided the necessary steps are taken.

For more information on trademarks, see: *www.wipo.int/trademarks*

How are trademarks relevant in ABS agreements?

Negotiations on access to and utilization of genetic resources and associated traditional knowledge primarily deal with rights over the resources or knowledge themselves, or with the outcomes of R&D involving them. However, the resources themselves, or compositions, processes or other results of the utilization of genetic resources and associated traditional knowledge, or their subsequent application and commercialization, may be distinguished through trademarks. Trademarks enable their owners to differentiate their products in the marketplace. They ensure that consumers can distinguish between products and facilitate their decision-making. Further, they can be used as part of a marketing campaign and form the basis for building a brand image and reputation. Trademarks may also be licensed to provide a direct source of revenue through royalties and may help in obtaining financing.

As illustrated in the sample clause in Box 7, a symbol associated with the resources could be registered as a trademark, and limitations on its use could be agreed in ABS agreements.

Box 7: Sample clause restricting the use of a symbol associated with the resources

"The user may use the resource but is restricted from using the trademark-protected symbol associated with the resource to market any outcomes of R&D arising from the utilization of the provided resource. Any use of the symbol has to be approved by the provider."

The checklist in Box 8 summarizes some key issues concerning trademarks that should be considered when negotiating ABS agreements.

Box 8: Checklist of trademark-related issues to consider in ABS negotiations

Authorization

- Does permission need to be sought to use a word or symbol and, if so, from whom and on what mutually agreed terms?
- What limitations, if any, should be imposed on use of the trademark, for instance to reflect cultural concerns?[7]

Ownership

- 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?

Exploitation model

- What would be the most appropriate commercial model for the exploitation of the trademark?
- Could the trademark be licensed or assigned?

Benefit-sharing

- How would any benefits arising from the use and licensing of the trademark be apportioned?

[7] These questions may be relevant, for instance, when dealing with indigenous signs that may be sacred or secret.

Another form of IP protection for distinctive signs are geographical indications and appellations of origin, but they are not addressed in this publication.

Copyright

What is copyright?

Copyright, or author's right, is a legal term used to describe the rights that creators have over their literary and artistic works.

What can be protected by copyright?

Works usually protected by copyright include:

- literary works such as novels, poems, plays, newspaper articles;
- artistic works such as paintings, drawings, photographs, and sculptures;
- computer programs, databases;
- films, musical compositions, and choreography;
- works of architecture; and
- advertisements, maps, and technical drawings.

Copyright protection extends to the expression of an idea, but not to the idea itself.

What conditions must be met to obtain copyright protection?

While criteria for protection may vary among jurisdictions, to qualify for copyright protection a work must generally be original and in many jurisdictions there is also a requirement that literary, artistic and dramatic and musical works be fixed in a material form.

What rights does copyright provide?

There are two types of rights under copyright:

- *economic rights*, which allow the rights owner to derive financial reward from the use of his or her works by others; and
- *moral rights*, which protect the non-economic interests of the author.

Most copyright laws state that the rights owner has the economic right to authorize or prevent certain uses in relation to a work or, in some cases, to receive remuneration for the use of his or her work.[8] The economic rights owner of a work can prohibit or authorize its:

- reproduction in various forms, such as printed publication or sound recording;
- public performance, such as in a play or musical work;
- recording, for example in the form of compact discs or DVDs;
- broadcasting by radio, cable or satellite;
- translation into other languages; and
- adaptation, such as turning a novel into a film screenplay.

Examples of widely recognized moral rights include the right to claim authorship of a work and the right to oppose changes to a work that could harm the creator's reputation.

How long does the protection last?

Economic rights have a time limit. These time limits can vary according to national law. In countries that are members of the Berne Convention,[9] the time limit should be at least 50 years after the creator's death. Longer periods of protection may, however, be provided at the national level. While the time limit for moral rights may also vary from country to country, in many countries the duration of moral rights is unlimited.

For more information about copyright, see: *www.wipo.int/copyright*

How is copyright protection relevant in ABS agreements?

Copyright may arise when information about genetic resources and accounts of traditional knowledge are written down or otherwise recorded. Access to and utilization of genetic resources and related information can result in the creation of original materials such as texts, technical drawings, databases or compilations that may be eligible for copyright

[8] For example, in many jurisdictions the rights owner has a right to receive fair remuneration when recorded works of music have been played, but not to authorize playing of such recordings in advance.

[9] The Berne Convention, adopted in 1886, deals with the protection of works and the rights of their authors. It provides creators such as authors, musicians, poets and painters with the means to control how their works are used, by whom, and on what terms. It contains a series of provisions determining the minimum protection to be granted, as well as special provisions available to developing countries that want to make use of them. Further information on the Berne Convention is available at: *www.wipo.int/treaties/en/ip/berne*

protection. In this case, copyright protects the way the information is expressed rather than the content of the information as such. This means that a third party will not be able to reproduce the information expressed in those materials without authorization, but they may make use of and build on that information.

Copyright may also arise when advanced characterization data about genetic resources are created, such as digital sequence information or other "omics" data, for example datasets characterizing the phenome, proteome or transcriptome of a given genetic resource. In such cases, and subject to applicable law, copyright may apply at several distinct levels of the generated information: copyright over the individual data, if they are original; copyright over compilations or collections of such data, which may themselves constitute an original work; and, in some jurisdictions, *sui generis* protection of non-original databases, where such protection is provided. The ways in which copyright and other IP are asserted for sequence information and its applications, in different sectors and under different scenarios, together with the implications for ABS, including monitoring, have been identified in existing fact-finding and scoping studies as one important area among several which warrant further and deeper investigation.[10]

In addition, copyright may apply to accounts of traditional knowledge or information on genetic resources that are organized in a systematic or methodical manner in a database, as well as compilations of information which by reason of the selection or arrangement of their contents constitute intellectual creations. In this case, copyright protection would apply to the database or compilation, but not necessarily to the information it contained.

Ownership of copyright in written materials, recordings, databases or compilations that may contain accounts of traditional knowledge or information about genetic resources initially vests in their author, who may or may not be the holder of the traditional knowledge associated with the genetic resources or the person who provided the information about the genetic resources. A copyright owner has the option to give, assign or license some or all of his or her economic rights.

[10] For one example, see a study by the Ad Hoc Expert Group on Digital Sequence Information on Genetic Resources of the CBD, "Fact-finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol" (CBD/DSI/AHTEG/2018/1/3), p. 57.

The checklist in Box 9 summarizes the key copyright-related issues that have to be taken into account in the context of ABS agreements to deal with some of the IP implications outlined above.

Box 9: Checklist of copyright-related issues to consider in ABS negotiations

Ownership

- Who owns the copyright in works that contain traditional knowledge associated with genetic resources and other information about genetic resources?

Joint authorship

- In cases of joint authorship, how will responsibilities flowing from co-ownership of copyright be apportioned?
- Can copyright material produced from the collaboration be assigned or otherwise licensed to third parties? If so, on what terms?

Benefit-sharing

- How will any monetary and non-monetary benefits arising out of the publication of copyright works be shared?

Trade secrets

What are trade secrets?

A trade secret is confidential information that provides the holder of the information with a competitive advantage. Trade secrets encompass, for example, manufacturing, industrial and commercial secrets. Typically, the unauthorized use of such information by persons other than the holder is regarded as an unfair practice and a violation of the trade secret. Depending on the legal system, the protection of trade secrets forms part of the general concept of protection against unfair competition or is based on specific provisions or case law on the protection of confidential information. The protection of trade secrets is, in general, not subject to formality requirements.

What can be protected by trade secrets?

The subject matter of trade secrets is usually defined in broad terms and includes:

- technical know-how (designs, formulas, manufacturing processes and other technical knowledge which results from experience and intellectual talent);
- data of commercial value (marketing plans, sales methods, distribution methods, consumer profiles, advertising strategies, lists of suppliers and clients and other business-related information that provides an advantage over competitors); and
- tests and other data submitted for the approval of pharmaceutical and chemical products for agriculture.

What conditions must be met to obtain protection under trade secrets law?

Trade secrets are protected without registration, that is, without any procedural formalities. A trade secret can be protected for an unlimited period of time. While conditions governing trade secrets vary from country to country, the following conditions would normally have to be met:[11]

- the information must be secret (in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to circles that normally deal with the kind of information in question);
- it must have commercial value because it is a secret; and
- it must have been subject to reasonable steps by the rightful holder of the information to keep it secret (e.g., through confidentiality agreements).

The sample clause in Box 10 provides an example of how these conditions can be used in the context of ABS agreements.

What rights do trade secrets provide?

Trade secrets are protected against unauthorized use and disclosure. If a trade secret holder fails to maintain secrecy, or if the information is independently discovered, becomes released or otherwise generally known, protection as a trade secret is lost.

[11] Article 39 TRIPS Agreement. See: *https://www.wto.org/english/docs_e/legal_e/27-trips.pdf*

How long does the protection last?

Trade secret protection is not limited in time. This is often regarded as an advantage compared with patent protection.

For more information about trade secrets, see: *www.wipo.int/sme/en/ip_business/trade_secrets/trade_secrets.htm*

Box 10: Sample clause on trade secrets

"The recipient agrees to use reasonable efforts (which shall be at least as great as the efforts to maintain the confidentiality of its own confidential information) to maintain the material technology in confidence, and to use the same only in accordance with this agreement. Such obligation of confidentiality shall not apply to information, which the recipient can demonstrate:

(a) was at the time of disclosure in the public domain;
(b) has come into the public domain after disclosure through no fault of the recipient or its employees;
(c) was known to the recipient or its employees prior to disclosure thereof by the provider; or
(d) was lawfully disclosed to the recipient without prior obligation of confidence by a third party who was not under an obligation of confidence to the recipient with respect thereto.

The foregoing obligations of confidentiality shall survive termination of this agreement."

San Diego State University (SDSU), Graduate and Research Affairs, Proprietary Material Transfer Agreement, clause 14; available at: *www.wipo.int/tk/en/databases/contracts/texts/sdsusimplemta.html*

Photos: © Hartmut Meyer/ABS Capacity Development Initiative

The Hwlenganton Medical Clinic in Porto Novo, Benin, combines traditional and modern medicinal approaches. Traditional medicine is well organized and plays an important role in healthcare in Benin, with traditional healers taking care of the vast majority of patients in the country. The State aims to strengthen this wealth of traditional knowledge, recognizing the traditional health practitioners' organization and offering an official market authorization for their products.

The development of protection schemes for traditional knowledge is seen as a major factor in the development of larger production facilities. In the absence of such protection schemes, the current practice is for recipes to be protected as family-owned trade secrets.

How are trade secrets relevant in the context of ABS agreements?

Access to and the utilization of genetic resources and associated traditional knowledge may raise trade secret issues among different actors. For cultural, economic or other reasons, the disclosure of traditional knowledge may not be allowed or may be limited to certain individuals within the community and/or specific purposes or circumstances. Moreover, organizations requesting access to genetic resources or associated traditional knowledge may intend to protect findings through trade secrets, which in turn may restrict how information is shared with or managed by the providers. As a result, ABS agreements may include confidentiality clauses, which are specific provisions on how to handle and provide protection to prevent the unwanted disclosure of such information.

As illustrated by the example in Box 11, trade secrets may also concern inventions based on the utilization of genetic resources that do not meet patentability criteria. For example, research may have confirmed biological activity in a biochemical that had already been mentioned in academic publications and thus would possibly not meet patentability criteria. Nevertheless, such results may be valuable and may need to be kept confidential as the company further explores the commercial applications of the molecule.

Box 11: Trade secrets arising from the utilization of genetic resources

Flavor and fragrance companies increasingly rely on patent protection for their innovations. For example, patents may be secured on synthetic molecules used in perfume manufacture. Nevertheless, trade secrets continue to play an important part in business strategies. Companies sometimes apply for patents covering only part of their inventions. This is part of a strategy aiming to prevent its competitors from gaining access to the know-how, which is considered a trade secret.

In ABS, trade secrets laws may be useful, particularly for smaller firms and individual inventors from provider countries. These actors often need to leverage their creativity and local knowledge most effectively by collaborating with large, well-established multinational corporations in user countries that are looking for fresh ideas and have the capacity to take these forward. In addition, some traditional knowledge is of a highly sacred and secret nature and therefore extremely sensitive and culturally significant and not readily available to the public. In such cases, using trade secrets protection may be a suitable way to secure protection for such knowledge.

Box 12 provides an indicative checklist of trade secrets-related issues that may be relevant in the process of negotiating and concluding ABS agreements. The list is not meant to be exhaustive, and other issues may come into play depending on the specific circumstances of each case.

Box 12: Checklist of trade secret-related issues to consider in ABS negotiations

- What information can and should be protected by trade secrets?
- Is the information truly confidential or secret?
- Are reasonable steps being taken to keep the information confidential?
- At what stage and on what conditions will users share trade secrets developed from using the genetic resources with providers?

3. Exploiting and managing IP rights

The previous section provided an overview of different forms of intellectual property rights that can arise in ABS agreements. But acquiring an IP right is not an end in itself. To take just one example, the granting of a patent does not in itself mean that an invention has economic value or will be commercially viable. It is therefore important to design appropriate strategies for exploiting and managing IP rights to ensure that they lead to the desired outcomes.

IP rights may be exploited and managed in many ways, for example manufacturing and distributing products that involve patented processes or components, licensing the IP rights for others to use in return for royalties, or selling the IP rights to realize a capital sum. IP rights may also be exercised defensively, to exclude others from certain areas of research or product development and so ensure freedom to operate. An IP management strategy must anticipate and clearly reflect the expectations and intentions of the contracting parties regarding how IP rights will be managed and used.

This section outlines some practical IP issues that may arise in the context of non-commercial and commercial ABS agreements, and situations involving change of intent and third-party transfers.

Non-commercial ABS agreements

ABS agreements for the utilization of genetic resources for non-commercial purposes normally exclude the use of IP rights over genetic resources. As illustrated in the sample clause in Box 13, if the research is for academic purposes only, a specific clause can be included in mutually agreed terms stipulating that no IP rights may be sought without obtaining prior informed consent from the provider. It is important that the resources be described precisely in the agreement, so that a court or arbitrator can identify what falls within the obligation.

Box 13: Sample clause restricting the claiming of IP rights

"The user shall not claim any intellectual property rights over the genetic resources in the form received or any progeny or derivatives thereof; and/or associated traditional knowledge, without the prior written consent of the provider."

Commercial ABS agreements

If the user seeks access to and utilization of genetic resources for applied research, then the mutually agreed terms must anticipate the IP implications arising from such use. This is especially important if the intended research aims to develop 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. For this reason, many ABS agreements dealing with the commercial utilization of genetic resources and associated traditional knowledge address IP issues in great detail. In some cases, terms for commercialization, including the commercialization of IP rights, are clearly specified. Numerous examples may be found in the WIPO Online Collection of ABS Contracts at: *www.wipo.int/tk/en/databases/contracts/*

Ethiopian coffee is one of the most valuable export products of Ethiopia. However, in the last century it faced quality problems because of the high level of mineral oil residues in the jute sacks in which coffee was packed. Mineral oils are used as lubricants during the production of jute coffee sacks. In cooperation with the Ethiopian University of Bahir Dar, Ethiopian jute producer G-Seven Trading & Industry P.L.C. undertook research on the suitability of extracts of Aloe species as a lubricant to replace mineral oils. The endogenous species *Aloe debrana* was chosen as a suitable source of lubricants and the company secured a national utility model on the use of the Aloe gel. [12] The Ethiopian Biodiversity Institute developed a sustainable harvesting method and entered into an ABS agreement with the company that covers the sharing of monetary benefits, among other things. Aloe is harvested by farmers and bought by the company at premium prices. Due to this innovation, Ethiopian coffee today no longer faces any quality problems related to its packaging in jute sacks.

[12] A utility model is an IP right similar to a patent but easier to obtain and offering a lower level of protection.

Jute sack production in Ethiopia using *Aloe debrana* extracts as a production lubricant.

Change of intent and/or transfer to third parties

Change of intent

Sometimes, the utilization of genetic resources for basic research may evolve into ideas, products or processes with potential commercial application, leading to applied research and product development. In such situations, a research agreement is often concluded for a first phase, and a second agreement concluded later on to address a change of intent that involves product development and commercialization. As illustrated by the sample clause in Box 14, these agreements often contain requirements for obtaining new prior informed consent and for the negotiation of new mutually agreed terms. In such cases, new terms and conditions relating to IP must be negotiated as part of the new mutually agreed terms.

Box 14: Sample clause on change of intent from non-commercial to commercial utilization

"The commercialization of the genetic material and related information is prohibited. Any change in utilization from noncommercial to commercial shall require a new prior informed consent in writing issued by the provider. In this case, the terms of such commercialization shall be subject to a separate agreement (MAT) [mutually agreed terms] between the involved parties."

Biber-Klemm, S., S.I. Martinez, A. Jacob, A. Jetvic, Swiss Academy of Sciences (eds.) (2010) *Sample ABS Agreement for Non-Commercial Research*. Bern, Switzerland; available at: *https://naturwissenschaften.ch/service/publications/36817-sample-abs-agreement-for-noncommercial-research-2010-*

Transfer to third parties

ABS transactions and biodiscovery processes often involve multiple parties interacting at various stages of the product development and value chains, and it is important at the outset to set clear terms and conditions for future transfers of genetic resources to third parties. In particular, it is important to ensure that any third-party beneficiary will be bound to the same IP obligations as the first user. Mutually agreed terms should clearly state that when a transfer is permitted, all the IP obligations of the initial user should flow to and must be respected by the third party. The provider may need to impose an obligation on the user not to seek to transfer the subject matter of the contract to a third party unless and until the third party has entered into a direct agreement with the provider undertaking to comply with the obligations of the transferor.

Ownership and licensing of IP rights

In the field of ABS, IP rights may often enable the exercise of ownership over intellectual outputs arising from the utilization of genetic resources. This can be done by creating, using and leveraging IP rights that enable their owner to enter into negotiations with others in order to advance in process and product development. Consequently, issues related to ownership and licensing of IP rights, as well as responsibility

for maintaining and exercising IP rights, should be carefully considered in ABS agreements.

Licensing issues to consider in ABS agreements

Exploiting an IP right, such as a patent based on the use of a genetic resource, can be costly and involve a considerable amount of commercial risk. For that reason, many users of genetic resources choose not to exploit IP rights themselves. Entering into a licensing agreement is one option that is often used to ensure the successful management and exploitation of IP rights in mutually agreed terms on ABS. A licensing agreement enables the owner of an IP right, such as a patent or trademark, to license that IP right to others, and for them then to develop and use it commercially. Generally, a license grants certain rights in property without transferring ownership of the property itself. This is typically done through a contract called a licensing agreement.

In the case of IP rights, a licensing agreement is an arrangement between the owner of an IP right (the licensor) and another (the licensee) who is authorized to use such rights in exchange for an agreed payment (fee or royalty).

Where a user owns IP rights in an innovation arising from the utilization of genetic resources, the licensee(s) will not normally have a direct contractual relationship with the provider of the genetic resources. However, the provider may want to determine in advance the permissible terms of such licensing activities, since they may be a form of commercialization triggering benefit-sharing obligations. It may thus be useful to ensure that terms and conditions for licensing an IP right are clearly stipulated as part of the IP clauses in ABS agreements.

Licensing agreements take many forms and may include a wide range of provisions depending not only on the parties' agreement, but also on the type of IP right being licensed, the sector of business and the applicable law.

In the case of ABS, licensing agreements are typically used to set out certain permitted uses of materials or rights that the provider is entitled to grant. Examples include agreements to license the use of genetic resources as research tools, of associated traditional knowledge or of other IP rights.

In the area of ABS, a licensing agreement will typically cover the following issues:

- What is being licensed?
- What type of license can be granted?
- What rights are granted and what restrictions are imposed or applicable?
- What fees and payment agreements apply?

A licensing agreement may include other aspects, but the above are some of the key issues that have to be carefully considered in the context of ABS agreements.

What is being licensed?

The license agreement should stipulate clearly what is being licensed. As illustrated by the sample clause below in Box 15, this may be done by defining processes and products covered by patent rights that are subject to licensing.

Box 15: Sample clause defining what is being licensed

"Licensed process: the processes covered by patent rights or processes utilizing biological materials or some portion thereof.

"Licensed products: products covered by patent rights or products made or services provided in accordance with or by means of licensed processes or products made or services provided utilizing biological materials or incorporating some portion of biological material."

Exclusive License Agreement (sample) – Harvard College, United States of America, Article 1, clauses 1.5 and 1.6; available at: *www.wipo.int/tk/en/databases/contracts/texts/harvardexlic.html*

What type of license can be granted?

Various types of licenses may be granted by a licensor – exclusive, sole, or non-exclusive:

- With an *exclusive license*, only the licensee is allowed to use the licensed IP or technology, that is, the licensor can no longer use it nor license it again to someone else.
- Once granted, a *sole license* prevents the licensor from licensing the IP to anyone else, but the licensor retains the right to use it him- or herself.
- A *non-exclusive license* can be granted by the licensor as often and to as many licensees as desired.

The sample clause in Box 16 is an example of a non-exclusive license granted for the use of biological materials.

Box 16: Sample clause granting a non-exclusive license

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

Non-exclusive License Agreement (sample) – Harvard College, United States of America, Article 3, clause 3.1; available at: *www.wipo.int/tk/en/databases/contracts/texts/harvardnonexlic.html*

In addition to these three types of license, the grant of a license may include the right of the licensee to "sub-license" the IP rights granted to it. The sub-license may encompass all or only a portion of the rights granted to the licensee.

What rights are granted and what restrictions are imposed or applicable?

The license needs to set out the exact rights that are (or are not) being granted. As illustrated by the sample clause in Box 17, rights may be exclusively linked to the use of licensed products or processes for research purposes and not for purposes of commercial manufacture or distribution.

Box 17: Sample clause identifying rights granted

"Research license means a non-transferable, non-exclusive license to make and to use the licensed products or licensed processes as defined by the licensed patent rights for purposes of research and not for purposes of commercial manufacture or distribution."

What fees and payment agreements apply?

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. Pricing should be realistic, reflecting possible delays with regulatory approvals (e.g., market approvals), especially in the biotechnology industry, and the fact that returns to the licensee can take many years to materialize. The sample clause contained in Box 18 provides an example of a clause where royalty payment percentages and timelines are agreed upon by the licensee and licensor.

Box 18: Sample clause specifying a royalty rate

"The licensee shall pay to Canada a royalty of X% per pound of certified seed resulting from the use of the Line Ten in the licensee breeding program, sold by the licensee for domestic sales and sold for export sales. The royalty shall be paid by the licensee to [...] by [date] of each calendar year."

Germplasm License Agreement for "Line Ten" between Her Majesty the Queen in Right of Canada (Licensor) and Company Canada Inc. (Licensee); available at: *www.wipo.int/tk/en/databases/contracts/texts/lineten.html*

Provisions for amicable settlement of disputes relating to IP rights in ABS agreements

In addition to ownership and exploitation of IP rights, it may be relevant to address dispute settlement issues related to IP rights in ABS agreements.

The range of measures may include dispute resolution mechanisms such as mediation, arbitration or litigation, and should also specify the jurisdiction that applies.

In the area of ABS, some IP issues may require specific dispute settlement clauses. For instance, there may be provisions for arbitration on whether or not to proceed with IP protection for a given innovation; whether or not a research outcome is derived from the use of genetic resources and is therefore covered by the agreement; or when certain obligations may be triggered, such as an agreement to license an IP right to a third party in the event that the user does not meet certain performance standards.

A good arbitration clause will normally contain the following information:

- the name of the appointing authority;
- the number of arbitrators;
- the place of arbitration;
- the languages to be used in arbitral proceedings; and
- the law governing the proceedings.

Sample clauses covering a range of dispute settlement mechanisms are available from the website of the WIPO Arbitration and Mediation Center: *www.wipo.int/amc/en/clauses*

4. Sector-specific IP issues

Sections 2 and 3 outlined challenges and opportunities to consider in negotiating IP-related clauses as part of mutually agreed terms. In such negotiations, providers of genetic resources should also keep in mind that the strategic importance of IP protection, the relevant types of IP rights and the way these rights are managed may differ significantly from case to case. In part, this reflects the particularities of research, development and commercialization activities in different industry sectors engaged in the utilization of genetic resources.

Biodiversity is a source of inputs, ingredients and inspiration for a range of industries, including pharmaceuticals, biotechnology, agriculture, cosmetics, and food and beverages.[13] These industries work with different types of genetic resources. They secure access to these resources in different ways and through different types of actors, and use the resulting information and innovation in different ways to develop products and processes.[14] These differences are critical in the negotiation of IP provisions.[15] For instance, in agriculture, the innovation process is usually incremental, arising from the contributions of a variety of actors and several genetic resources, in several locations and at different points in the R&D process.[16] IP provisions in material transfer or other agreements used to access genetic resources – or indeed, the entire agreements – are therefore often based on standard clauses, as a way

[13] Industrial sectors involved in the utilization of genetic resources have been identified and explored in a range of international meetings and publications. Meetings include the 2008 gathering of the CBD Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, in Windhoek, Namibia, and an Informal Meeting for the Implementation of Articles 19 and 20 of the Nagoya Protocol convened in 2013 by the Government of Japan and the United Nations University Institute for the Advanced Study of Sustainability (UNU-IAS) in collaboration with the CBD Secretariat. Among the various publications, it is worth noting the series on "Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change" published by the CBD Secretariat and cited extensively in this section.

[14] A series of assessments of the utilization of genetic resources in various sectors, including pharmaceuticals, agriculture, botanicals and food and beverages, with key points for policymakers to consider was commissioned by the ABS Capacity Development Initiative and is available via the "Studies" menu at: *www.abs-initiative.info/knowledge-center/publications*

[15] L. Orsenigo and V. Sterzi (2010). Comparative Study of the Use of Patents in Different Industries. *KITeS Working Papers No. 33/2010.* KITeS, Centre for Knowledge, Internationalization and Technology Studies, Università Bocconi, Milan, Italy; available at: *http://is.jrc.ec.europa.eu/pages/ISG/patents/documents/OrsenigoandSterzi2010.pdf*

[16] R. Wynberg (2013). Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: Agriculture. Secretariat of the Convention on Biological Diversity, Montreal, Canada; available at: *https://www.cbd.int/abs/doc/protocol/factsheets/policy/abs-policy-brief-agriculture-web-en.pdf*

of avoiding long and complex negotiations.[17] In contrast, IP provisions in the pharmaceutical sector are nearly always negotiated individually, though the starting point may be a model agreement.

To take another example, among different types of IP rights, patents are likely to be more relevant in mutually agreed terms involving sectors where R&D costs are high but imitation is cheap. This is the case in the pharmaceutical sector. In industrial biotechnology, some companies may conduct R&D entirely in-house and protect their innovation primarily through secrecy.[18]

This section thus looks at how selected industrial sectors engage in the utilization of genetic resources and analyzes how these characteristics may affect how IP issues are addressed in mutually agreed terms. The aim is not to provide a complete map of the use of IP in each of these sectors, but rather to highlight some relevant challenges and opportunities in the interface between ABS and IP. Sample clauses are provided to illustrate how IP issues are dealt with in practice in agreements used by companies working in these different sectors.

Pharmaceuticals

Substances derived from plants, animals or microorganisms were the earliest medicines. They often remain a starting point for drug discovery and constitute the active components of many pharmaceutical products. For example, 49 percent of small molecules identified for cancer treatment since the 1940s are natural products or directly derived from natural products.[19] Natural products also play other roles in pharmaceutical innovation, including as elements of vaccines, inactive parts of final products and tools in the research and production processes.

[17] ICC (2008) Compilation of submissions by parties, international organizations, indigenous and local communities and stakeholders to a meeting of the CBD Technical Experts Group on Concepts, Terms, Working Definitions and Sectoral Approaches, Windhoek, December 2-5, 2008, "Access and Benefit Sharing: Sectoral Approaches, Concepts, Terms, Working Definitions"; available at: *https://www.cbd.int/doc/meetings/abs/absgtle-01/official/absgtle-01-02-en.pdf*

[18] S.A. Laird (2013). *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: Industrial Biotechnology*. Secretariat of the Convention on Biological Diversity, Montreal, Canada; available at: *www.cbd.int/abs/policy-brief/default.shtml/*

[19] D. Newman and G. Cragg (2016). Natural products as sources of new drugs over the 30 years from 1981 to 2014. *Journal of Natural Products*, 79(3), 629-661; available at: *http://pubs.acs.org/doi/pdf/10.1021/acs.jnatprod.5b01055*

Approaches and trends in the utilization of genetic resources

A 2016 report estimates that almost 18,000 plants are currently used in traditional and modern medicine for humans and animals.[20] In recent decades, scientific and technological advances have expanded interest to other components of biodiversity, namely marine and terrestrial microorganisms.[21] New technologies and scientific advances in the understanding of genomics allow for a much more comprehensive study of microorganisms and a more profound look into the biochemistry of each organism's genome to detect a wider range and number of biochemical compounds or proteins of potential pharmaceutical application. The use of genomics, proteomics,[22] metabolomics[23] and transcriptomics[24] are now regular features of natural product research. Along with microorganisms, marine toxins, venoms and other naturally occurring biological agents are used in pharmacological research and sold as research biochemicals.

A *Prunus africana* plantation in Uganda.

[20] Royal Botanical Gardens Kew (2016). *State of the World's Plants*. Board of Trustees of the Royal Botanical Gardens Kew, London, United Kingdom; available at: *https://stateoftheworldsplants.com/report/sotwp_2016.pdf*

[21] Ibid.

[22] Proteomics is the large-scale study of proteins. The 'proteome' of an organism is the entire set of proteins produced or modified by that organism.

[23] Metabolomics is the study of chemical processes involving metabolites, the small molecule intermediates and products of metabolism. The 'metabolome' represents the complete set of metabolites in a biological cell, tissue, organ or organism, which are the end products of its cellular processes. Thus, metabolomics is the "systematic study of the unique chemical fingerprints that specific cellular processes leave behind", i.e. the study of their small-molecule metabolite profiles.

[24] The transcriptome is the set of all RNA molecules in one cell or a population of cells. Study of the transcriptome is referred to as transcriptomics.

These trends have significant implications for how access to genetic resources is sought in the pharmaceutical sector. New research tools allow novel insights from existing compound libraries, increasing the importance of *ex-situ* collections or other intermediaries as a source of genetic resources for pharmaceutical R&D. In the context of the Nagoya Protocol negotiations, pharmaceutical companies reported that field collection no longer takes place on any scale and the role of traditional knowledge in drug discovery is diminishing.[25] Nevertheless, studies looking at recent discoveries and innovations, as well as partnerships and collaborations in the sector, suggest that field collection of genetic resources for pharmaceutical use remains significant, though it may be conducted not directly by pharmaceutical companies but through commercial or academic partners.[26] The utilization of genetic resources in the pharmaceutical sector may thus involve various actors linked by alliances and partnerships. Larger pharmaceutical companies may license compounds that were identified by smaller discovery companies and academic research laboratories.[27]

Research and development activities in this sector remain conditioned by high risk and high investment, as well as long R&D cycles. The process from drug discovery to manufacturing may take up to 15 years.[28] For every 5,000-10,000 compounds that enter the drug development pipeline, only a few may receive approval. Even medicines that reach clinical trials have only a 16 percent chance of being approved. Only 2 in every 10 marketed drugs return revenues that match or exceed R&D costs. Scientific and technological developments have also had significant implications for the speed, scale and cost of research and development.[29]

[25] S.A. Laird (2013). *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Pharmaceutical Industry.* Secretariat of the Convention on Biological Diversity, Montreal, Canada; available at: *www.cbd.int/abs/policy-brief/default.shtml/*

[26] See, for instance, the report of the meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches to the seventh meeting of the Ad Hoc Open-Ended Working Group of the CBD on Access and Benefit-Sharing, April 2-8, 2009 (UNEP/CBD/WG-ABS/7/2); available at: *https://www.cbd.int/doc/meetings/abs/abswg-07/official/abswg-07-02-en.pdf*

[27] Ibid

[28] Ibid

[29] See, e.g., findings in Newman and Cragg (2016), supra note 50, and S.-K. Kim (ed.) (2015) *Handbook of Anticancer Drugs from Marine Origin.* Springer International Publishing, Switzerland, which notes that pharmaceutical companies such as Eisai, Eli Lilly, Novartis and Pfizer all have therapeutic compounds of marine origin under development.

Harvesting *Prunus africana* bark in Cameroon.

A meeting of *Prunus africana* farmers in Uganda.

Photos: © Hartmut Meyer/ABS Capacity Development Initiative

Prunus africana bark storage in Uganda.

Since the late 1960s, extracts from the bark of the *Prunus africana* tree have formed the basis of a drug against prostate enlargement, a condition that favours the development of prostate cancer. The raw material is mainly harvested in Cameroon, Uganda and the Democratic Republic of Congo. Three companies in the European Union now produce the extracts and medicine. Related patents have expired, and ABS contracts have never been negotiated. The *Prunus* value chain faces challenges in terms of sustainability. It is important that the trees grow in agroforestry schemes such as the one in Uganda pictured here, but the lack of benefit-sharing agreements with the providers of the genetic resource is a threat to sustainability. Fair and equitable benefit-sharing directed to the protection and sustainable use of the trees would support the long-term needs of all stakeholders and consumers in the value chain.

IP considerations

Pharmaceuticals is one of the sectors in which IP is seen as a key instrument for securing the economic benefits of innovation. The pharmaceutical business model relies primarily on patents and data protection.[30] These tools are meant to protect the outcomes of expensive research and development processes, which competitors could easily take up given the low production costs for pharmaceuticals.[31]

In this context, agreements on licensing, collaborative ventures and transfer of technology are commonly used to facilitate continuing innovation and manage collaborative research between large pharmaceutical companies, biotechnology companies and public research organizations.[32] For example, an analysis of pharmaceutical patents from 1931 to 2013 shows that the first patents for the majority of new molecular entities were assigned to pharmaceutical companies (81.4 percent), followed by academia (10.1 percent) and the biotechnology industry (8.5 percent).[33] However, looking at more recent trends, an analysis of patents on biologics-based medicines between 1981 and 2013 reveals that academic institutions (including government laboratories) were the source of approximately a quarter of inventions, with pharmaceutical companies and biotechnology companies sharing the remainder more or less equally.[34]

It is clear that IP provisions are critical for both users and providers as part of the terms and conditions for the utilization of genetic resources in the pharmaceutical sector. This is true irrespective of whether such terms and conditions are set out in material transfer agreements, research collaboration or benefit-sharing agreements, depending on the legal and regulatory requirements.

[30] See Laird, Bioscience at a Crossroads: The Pharmaceutical Industry, supra note 25.

[31] S.A. Laird (2015). Access and Benefit Sharing: Key Points for Policy Makers – The Pharmaceutical Industry; available at: *https://www.researchgate.net/publication/303315541_Access_and_Benefit_Sharing_Key_Points_for_Policy_Makers_The_Pharmaceutical_Industry*

[32] Data protection refers to the protection of undisclosed test or other data submitted as a requirement for the commercialization or marketing of pharmaceutical or other chemical products against unfair commercial use and/or disclosure.

[33] See, e.g., Pharmaceutical Research and Manufacturers of America (PhRMA) "Advocacy – Intellectual Property" *www.phrma.org/innovation/intellectual-property*

[34] I. Cockburn (2009). Intellectual property rights and pharmaceuticals: challenges and opportunities for economic research. In *The Economics of Intellectual Property: Suggestions for Research and Developing Countries and Countries with Economies in Transition.* World Intellectual Property Organization, Geneva, Switzerland; available at: *www.wipo.int/export/sites/www/ip-development/en/economics/pdf/wo_1012_e.pdf*

For users, clarity on IP rights is an essential part of the legal certainty required prior to investing time, effort and money in mounting a pharmaceutical research and development project. A key concern for users in the pharmaceutical sector is to secure confidentiality of research and development outcomes and results, at least until patent applications are filed, which is fundamental to protecting potential IP rights and other business interests.

Providers need to ensure that mutually agreed terms adequately foresee the ownership and scope of the IP rights that may potentially result from research and development activities, as well as the possibility that users may in some instances license such IP rights to others.

On ownership, provisions may be included, among other things, to restrict patenting of biological or genetic material as transferred to the user, as the sample clauses in Box 19 illustrate. However, agreements in this sector will likely require that the user be allowed to patent inventions made in the course of research and development. Agreeing on joint ownership of resulting patents, though mentioned in the Nagoya Protocol as a possible benefit-sharing mechanism, tends to be difficult in the pharmaceutical sector, where companies are particularly wary of legal complication and uncertainty. For example, though most countries require the co-owner of a patent to seek consent of the other co-owner in order to license an interest, this is not the case in the United States of America (U.S.), where one joint owner may grant a license without the consent of the other and without having to account for any royalties or other payments.[35] Also, in most jurisdictions a co-owner can exploit the patent on its own account without consent, and without having to account for any profits it makes from that exploitation. An option in some cases may be mutually agreed terms that vest patents in the user but require some type of license, whether free of royalties or under preferential terms, to be granted to the provider. In such cases there would be no joint ownership of patents, which some providers might regard as inequitable. Nevertheless, this approach may – from the perspective of the provider – have the advantage of requiring the user to file for, maintain and enforce the patents while allowing the provider to make, use, sell or import the protected invention at no or limited cost.

[35] P. Mendes (2005). Licensing and technology transfer in the pharmaceutical industry. In *Exporting Pharmaceuticals: A Guide for Small and Medium-sized Exporters* (Trade Secrets Series). International Trade Centre UNCTAD/WTO, Geneva, Switzerland.

On licensing of patents, providers should ensure that any relevant conditions established in the mutually agreed terms are transferred to the licensee. Negotiations of these conditions may also include benefit-sharing requirements linked to monetary benefits of patent licenses. For example, in the pharmaceutical sector the licensor typically receives an upfront fee, milestone payments for specific clinical outcomes and sales-based royalties as consideration for the license.[36] It may be useful for mutually agreed terms to foresee the possibility of the user out-licensing its inventions and consider how fees and milestone payments must be determined and shared.

Box 19: Sample clauses on ownership of IP rights in the pharmaceutical sector

The following clauses show some of the possible approaches to ownership of IP rights in the context of mutually agreed terms:

- "The recipient agrees not to claim ownership over the material, nor to seek intellectual property rights over the material and/or its related information."
- "If research and development on the material results in products and processes that are patentable (i.e., novel, inventive and with practical utility), the recipient will own any resulting patents or other intellectual property rights thereon."
- "In the case of a patentable invention resulting from the activities undertaken as a result of this agreement, the recipient is free to apply for patents with regard to such invention in its name and at its expense. Any such applications for patent should be promptly notified to the provider and include references to the country of origin of the material, as well as any information on traditional uses considered in the research and development process."
- "If the recipient wishes to protect the results of its investigations based on the material received, by means of some system of intellectual property protection, he will provide prior notice to the provider. Any intellectual property rights sought with regard to results of investigations must conform to national and international legislation on access and benefit sharing, as well as to the terms of this agreement."

[36] LES (Licensing Executives Society) (2008). Biopharmaceutical royalty rates and deal terms report. Available at: *www.lesi.org/docs/lesi-updates-and-news-documents/2008biopharmaceauticalroyaltyratedealterms-110108.pdf*

Adapted from Union for Ethical BioTrade (UEBT) (2013) Using Material Transfer Agreements to put Access and Benefit Sharing in Practice; available at: *http://ethicalbiotrade.org/dl/UEBT_MTAs-and-ABS-issues_Final- June-2013.pdf* and *http://ethicalbiotrade.org/resources/#6*

Industrial biotechnology

Industrial biotechnology refers to the set of practices that use living cells (microorganisms such as bacteria or yeast) or components of cells (such as enzymes) to generate industrial products and processes. These practices do not constitute an industrial sector as such, but are used across other industrial sectors, including chemicals, plastics, food, cleaning products, cosmetics and energy. For example, industrial biotechnology has been used to create plant-based biodegradable plastics, produce transport fuels from biomass feedstocks and treat fibers during textile processing.[37] It is estimated that more than 500 consumer products are made using microbial enzymes developed through industrial biotechnology.[38]

Approaches and trends in the utilization of genetic resources

To find new and interesting enzymes for use in industrial biotechnology, researchers may explore existing collections of microorganisms or those in the natural environment.[39] Leading companies in the sector use genetic material from all over the planet, because diverse and extreme ecosystems like volcanoes, deep-sea hydrothermal vents, rain forests and deserts mimic the harsh temperature and pH conditions found in the industrial processes that microbes would need to survive.[40]

[37] See a webpage produced by the Department of Industry, Innovation and Science of the Australian Government on "Industrial Biotechnology and Biomass Industries": *www.industry.gov.au/industry/IndustrySectors/nanotechnology/IndustrialBiotechnology/Pages/default.aspx*

[38] See Laird, Bioscience at a Crossroads: Biotechnology, supra note 18.

[39] See a webpage of the Biotechnology Innovation Organization, "What is Industrial Biotechnology?": *https://www.bio.org/articles/what-industrial-biotechnology.* Exploring microorganisms in the natural environment may involve studying samples of soil, water, sediment, leaf litter or other materials.

[40] See, e.g., BASF's introduction to its work with enzymes, "What We Do": *www.basf.com/tw/en/products-and-industries/general-business-topics/enzymes.html*

Photos: © Hartmut Meyer/ABS Capacity Development Initiative

The hot, sulfurous springs at Lake Bogoria in Kenya are the target of many scientific excursions to collect extremophile microorganisms. Biotechnology institutes and industries are interested in researching and exploiting characteristics of extremophile microorganisms such as their endurance of heat and acids. Kenya's authorities currently negotiate ABS agreements regarding these and other genetic resources which include IP clauses to ensure benefit-sharing from future license fees and industrial commercialization. The Endorois Welfare Council, representing indigenous peoples from the area, developed a Biocultural Community Protocol which will support the Endorois communities in participating in the ABS negotiations.

Once isolated, enzymes can be characterized for their ability to function in specific industrial processes and, if necessary, improved with biotechnology techniques. Since less than 1 percent of microbes can be cultivated through standard laboratory techniques, most companies now use metagenomics as an alternative to conventional microbe screening.[41] In other words, companies prepare a genomic library and conduct systematic screening based on either function or sequence approaches.[42] Research and development often takes place within complex, global webs of partnership, investment and collaboration, often focused on sharing or getting access to specific technologies or products.[43]

After the research and development process, industrial enzymes are usually manufactured and used within the same company and its partners. Most industrial biotech products take 2 to 5 years to reach the market, though for some products it may take as long as 10. They are thus quicker to develop than pharmaceuticals and require less investment and testing. On the other hand, industrial biotechnology products also normally generate less revenue than pharmaceutical products.

IP considerations

As in the pharmaceutical sector, patent protection is often essential for the development or commercialization of industrial biotechnology processes and products. Indeed, the number of patents granted in biotechnology is rising at a far higher rate than the overall increase in the number of patents across economic sectors.[44] Moreover, there are various types of companies that secure patents over industrial biotechnology products. Large industrial biotechnology companies view patents as a tool to secure freedom to operate,[45] create value and limit competitors' activities.[46]

[41] J.L. Adrio and A.L. Demain (2014). Microbial enzymes: tools for biotechnological processes. Biomolecules, 4(1), 17-139; available at: *www.ncbi.nlm.nih.gov/pmc/articles/PMC4030981/*

[42] There are two basic types of metagenomics studies. Sequence-based studies involve sequencing and analysis of DNA from environmental samples. These studies can be used to assemble genomes, identify genes and compare organisms of different communities. Function-based studies involve screening for a particular function or activity, such as proteins involved in antibiotic resistance, vitamin production and pollutant degradation.

[43] For example, in 2013, BASF announced three separate partnerships on industrial biotechnology, including the acquisition of detergent enzyme technology from Henkel, the licensing of a technology platform from Dyadic and a research and development pact with Direvo. See, e.g., J. Lane (2013). Fearsome foursome: BASF, with 3 new deals, heads for the big league in industrial enzymes. *BiofuelsDigest*; available at: *www. biofuelsdigest.com/bdigest/2013/05/16/basf-with-three-new-deals-positions-to-become-a-major-player- in-industrial-enzymes/; see also Laird, supra note 18.*

[44] See, e.g., OECD (2002). Genetic Inventions, Intellectual Property Rights and Licensing Practices.

[45] Securing "freedom to operate" i.e., to ensure that the commercial production, marketing and use of their new product, process or service does not infringe the IP rights of others. See *WIPO Magazine*, September 2005, Launching a New Product: Freedom to Operate; available at: *www.wipo.int/wipo_magazine/en/2005/05/article_0006.html*

[46] See Orsenigo and Sterzi, supra note 15.

IP-related provisions may often come up in the negotiation of mutually agreed terms for access to genetic resources to be utilized in industrial biotechnology. For example, mutually agreed terms on access to soil, water or other samples with the purpose of screening for microorganisms and identifying promising enzymes should include provisions on the ownership of patents resulting from these research and development activities. Parties in such negotiations should also bear in mind that patents in industrial biotechnology are not necessarily valuable in terms of yielding monetary benefits; they are not always exploited commercially, but may instead serve as a barrier to keep competitors from entering the market.[47] Moreover, industrial biotechnology companies may also choose not to patent certain inventions, relying instead on trade secrets.[48]

Bear in mind also that licensing of patents is a common practice in the industrial biotechnology sector. Licensing may be used for collaboration with other companies that have complementary technologies or, particularly for smaller companies, as a source of revenue. As in all patent licensing, there are various possible approaches and payment structures. Patent rights may be licensed on exclusive or non-exclusive bases. Licensing may be subject to temporal or territorial limitations. A license may cover the entire invention or only some of its elements.

There are several types of royalties or other license fees. Some fees are independent of the commercialization of the licensed innovation or related products, such as upfront royalties, milestone payments and minimum royalties. Other royalties are established as a percentage of gross or net revenues derived from the commercialization of the licensed innovation or related products. The royalty rate – that is, the precise percentage or amount of royalty charged – varies from agreement to agreement. Studies show a wide range of royalty rates in pharmaceutical and biotechnology licensing agreements, with the average being 7 percent of gross sales (see Box 20). Different types of royalties may be combined. All of these factors mean that a range of potential licensing scenarios may need to be considered in negotiations in order to ensure that any ABS provisions are sufficiently flexible and comprehensive.

[47] Ibid

[48] See Laird, Bioscience at a Crossroads: Biotechnology, supra note 18.

Interestingly, biotechnology license agreements are generally established for early-stage technology, where the path to a commercial product is not entirely certain. This challenge is addressed through "term sheets" which summarize the issues that the parties consider as the most important aspects of the deal.[49] Although generally non-binding, a term sheet is seen to guide and focus the negotiation process in licensing agreements. Such an approach may also be useful in negotiations of mutually agreed terms linked to biotechnology, as commercialization prospects are also likely to be uncertain during such negotiations. Effective term sheets should be customized, but models and tips are available from various sources.[50]

Box 20: Royalty rates in pharmaceutical and biotechnology licensing agreements

	Rate (% of gross sales)
Average royalty	7%
Median royalty	5%
Maximum royalty	50%
Minimum royalty	0%

Source: Based on a review of 458 agreements conducted by David Weiler, quoted in Intellectual Property Research Associates (IPRA) (2010) *Royalty. Rates for Pharmaceuticals & Biotechnology* (7th edition).

Biotechnology production facilities at INBio, Costa Rica.

[49] V. Drozdoff and D. Fairbairn (2015). Licensing biotech intellectual property in university–industry partnerships. *Cold Spring Harbor Perspectives in Medicine;* available at: http://perspectivesinmedicine.cshlp.org/content/5/3/a021014.full

[50] See, e.g., this model term sheet from the Biotechnology Industry Organization website: *https://www.bio.org/sites/default/files/files/TERM%20SHEET%20EXAMPLE_CUPIT%20AND%20SINATRA.pdf*

Insect collection at INBio, Costa Rica.

Photos: © Hartmut Meyer/ABS Capacity Development Initiative

Microbial collection at INBio, Costa Rica.

The Instituto Nacional de Biodiversidad (INBio) in Costa Rica has built up a large collection of national genetic resources and scientific capacities to support valorization of its genetic resources.

Agriculture

The goals of biodiversity-based innovation in the agricultural sector range from yield improvement and quality enhancement to pest control. In plant breeding, research and development focuses on developing new crop varieties with improved performance or efficiency, through advanced marker-assisted selection and other breeding techniques.[51] In crop protection, the focus of plant breeding is on developing genetic traits aimed at controlling pests, particularly insect resistance and inducing herbicide tolerance. Research and development in crop protection also involves activities that are more closely related to research and development for products like pharmaceuticals; for example, identifying new active ingredients for pesticides and herbicides (see Box 21 on page 73).

Approaches and trends in the utilization of genetic resources

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

A growth chamber.

[51] See Wynberg, Bioscience at a Crossroads: Agriculture, supra note 16

Technology has dramatically changed plant innovation in recent decades, as has the growing role of private investment. Research conducted by the Agricultural Science and Technology Indicators Initiative shows that private investment in agricultural research and development rose 26 percent between 2000 and 2008, and more than a fifth of all spending worldwide is now private.[52] Most private sector research focuses on export commodities or high-value seed. Large seed companies look for traits that improve performance and farming efficiency to develop high-value commercial lines.

In terms of access to genetic resources, a very significant source of material are *ex-situ* collections throughout the world. Smaller seed companies and public institutions rely primarily on public sector collections, including CGIAR (formerly the Consultative Group for International Agricultural Research) centres.[53] However, public collections often maintain and increase their genetic material through field collection, generally working with farmers for their knowledge and local varieties.[54]

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

A mobile tissue culture box for farm-based multiplication of improved local plant varieties in Jamaica.

[52] T. Paul Cox (2013). The new world map of agricultural R&D investment. *New Agriculturalist;* available at: *www.new-ag.info/en/focus/focusItem.php?a=2869*

[53] See Wynberg, Bioscience at a Crossroads: Agriculture, supra note 25.

[54] For example, as part of conservation projects, public collections engage in national or international collection activities, carry out germination tests, and share among participants seeds for their long-term conservation.

Larger seed companies tend to rely on their own collections. It is worth noting that, although there may now be little reference to or use of farmers' knowledge, the material will most likely have been collected originally on the basis of such knowledge.

There is growing interest and investment in crop wild relatives, because these species contain important genes for stress resistance, improved productivity and nutritional properties. The effort required to use landraces or wild relatives for the development of commercially viable resources remains considerable, but molecular genetic techniques are likely to help speed up the process.[55]

Box 21: Crop protection

Crop protection involves research and development of active ingredients and biocontrol agents. This is an important subsector within agriculture, with global sales – which focus primarily on herbicides, fungicides and insecticides – having grown from USD 25 billion in 1990 to over 60 billion in 2013.

It has been noted that technologies used for research and development in the sector are evolving, with use of genomics, combinatorial chemistry and genetic engineering. At the same time, the development pipeline is seen to be shrinking: in 2013, there were only half the number of active ingredients in the pipeline as a decade earlier. Though crop protection once primarily involved patent-protected active ingredients, the use of off-patent, generic molecules has grown significantly over time.

[55] See Wynberg, Bioscience at a Crossroads: Agriculture, supra note 25.

IP considerations

Recognizing the special nature of plant genetic resources for food and agriculture, and the need for distinctive solutions for their conservation and sustainable use and the fair and equitable sharing of the benefits they bring, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) includes a Multilateral System for ABS.[56] The Multilateral System of the ITPGRFA responds to countries' interdependence in relation to genetic resources for food and agriculture and the need to facilitate flows of these resources for agricultural research and breeding activities. It is a global pool of some of the most important crop genetic resources for food and security which is shared and managed jointly by countries that adhere to the treaty.[57]

One of the key elements of the Multilateral System is that it eliminates complicated procedures and time-consuming negotiations of specific contracts for access to specific plant genetic resources for food and agriculture. A recipient who would like to receive a given crop sample from a certain gene bank collection, for example, can simply do so according to the terms of the Standard Material Transfer Agreement (SMTA).

This SMTA is a mandatory model for parties wishing to provide and receive material under the Multilateral System. It is a standard contract, negotiated and agreed internationally, which may not be varied or abbreviated in any way.[58] The SMTA sets out the conditions for access and includes provisions on benefit-sharing, dispute settlement and IP. In particular, Article 6.2 restricts recipients of genetic resources through the Multilateral System from claiming any IP right that would limit the freedom of others to obtain samples of the same materials through an SMTA "in the form received".

Recipients are able to obtain IP rights on modified derivatives. However, according to Article 6.7 of the SMTA, if such IP rights result in the commercialization of a product that is not available to others for further re-

[56] For a summary of the main issues and provisions in the ITPGRFA, see Food and Agriculture Organization (2011). *Introduction to the International Treaty on Plant Genetic Resources for Food and Agriculture.* FAO, Rome, Italy; available at: *www.fao.org/docrep/016/i2631e/i2631e00.pdf.* The crops that form part of the Multilateral System are defined in a list contained in Annex I of the treaty. Together, the crops listed in Annex I account for more than 80 percent of human calorie intake from plants. Note that the Multilateral System is currently being renegotiated.

[57] See note 56 above.

[58] Discussions are ongoing under the multilateral system on how certain SMTA provisions could be revised.

search and breeding, recipients are bound to share benefits. The term "available without restriction" used in Article 6.7 of the SMTA is defined to exclude restrictions of a legal, contractual or technological nature. Some of the SMTA clauses related to IP are shown in Box 22.

Box 22: Selected IP provisions in the SMTA

"6.2 The recipient shall not claim any intellectual property or other rights that limit the facilitated access to the material provided under this agreement, or its genetic parts or components, in the form received from the Multilateral System.

"6.7 In the case that the recipient commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material as referred to in Article 3 of this agreement, and where such product is not available without restriction to others for further research and breeding, the recipient shall pay a fixed percentage of the sales of the commercialized product into the mechanism established by the governing body for this purpose, in accordance with annex 2 to this agreement.

"6.10 A recipient who obtains intellectual property rights on any products developed from the material or its components, obtained from the multilateral system, and assigns such intellectual property rights to a third party, shall transfer the benefit-sharing obligations of this agreement to that third party."

Standard Material Transfer Agreement of the ITPGRFA; available at: *http://www.fao.org/3/a-bc083e.pdf*

Beyond those crops and forages that are included in the multilateral system, plant genetic resources for food and agriculture fall within the Nagoya Protocol and its implementing laws and regulations at the national level. Few of these national rules currently exclude or establish separate systems for the agricultural sector. That said, material transfer agreements used to access genetic resources from *ex-situ* collections may, in some cases, be recognized as mutually agreed terms.

In line with international rules, the sharing of germplasm and other material increasingly takes place under material transfer agreements.[59] This allows organizations to share biological material such as seeds, cell-lines or germplasm for evaluation or further development while agreeing on terms of use for the material and information, and on any related intellectual property. However, most material transfer agreements do not address the rights of the original providers of the genetic resources to the *ex-situ* collections.

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

A biotechnology laboratory in Mali.

Different templates for material transfer agreements exist and may be used. Most material transfer agreements include IP provisions. For example, some material transfer agreements contain provisions preventing patenting of the transferred material or of certain kinds of derived products, as the sample clause in Box 23 illustrates. Other material transfer agreements allocate ownership over potential IP rights like patents and parameters for sharing benefits. Yet, others leave these issues to be

[59] In part, this is due to the SMTA being voluntarily used for the exchange of non-Annex I materials that are held by the CGIAR. Additionally, there is voluntary inclusion of other material held by Contracting Parties and other natural and legal persons.

negotiated if and when interesting R&D results arise or potential commercial products are created, as shown in the sample clause in Box 24. Note, however, that a postponement of agreement on the allocation of such rights may result in an agreement that is not precise enough to be capable of effective enforcement.

Box 23: Sample material transfer agreement provision preventing patenting

"The recipient shall own the progeny or germplasm which are not essentially derived from the material. The recipient agrees that it [...] 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."

Adapted from Material Transfer Agreement (Germplasm and Unregistered Lines) between the Department of Agriculture and AgriFoods, Canada (AAFC) and several public breeding institutions.

Box 24: Sample material transfer agreement provision on agricultural research and intellectual property

"The recipient agrees that it will enter into equitable arrangements with the provider in relation to the following matters:

- the allocation of ownership of intellectual property in the material;
- the terms of any licenses between the parties to use or exploit the intellectual property;
- the terms of any licenses of other intellectual property owned or licensed by either of the parties which are necessary for the utilization of the material; and
- the allocation of costs relating to the application for and maintenance of the intellectual property rights between the parties."

Adapted from Standard Conditions for Project Agreements between the Australian Centre for International Agricultural Research (ACIAR) and the Commissioned Organisation.

Cosmetics and personal care

Cosmetics and personal care products refer to products intended for application to the human body for cleansing or beautifying purposes.[60] Included in this definition are skin moisturizers, perfumes, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colorings, toothpastes and deodorants. Natural ingredients remain just a fraction of the thousands of ingredients available for such products,[61] but some reports indicate that they are being used more and more, responding to a growing consumer interest in health and well-being, as well as concerns about ethical sourcing and sustainability.[62]

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

Traditional cosmetic products at a Nigerian market.

Approaches and trends in the utilization of genetic resources

Innovation with natural ingredients is an important trend in cosmetics. In a sector characterized by short product life-cycles, companies are under pressure to constantly differentiate products, attract new customers and gain a marketing advantage. However, growing use of natural ingredients

[60] As defined by the United States Food & Drug Administration: *www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm2005209.htm*

[61] Wynberg and Laird quote natural ingredients as constituting 7 percent of the cosmetic ingredients market: R. Wynberg and S.A. Laird (2013). *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Cosmetics Sector.* Secretariat of the Convention on Biological Diversity, Montreal, Canada; available at: *www.cbd.int/abs/policy-brief/default.shtml/*

[62] Union for Ethical BioTrade (UEBT) (2016). *Biodiversity Barometer 2009-2016.* UEBT, Amsterdam, Netherlands; available at: *http://ethicalbiotrade.org/dl/Baro-2016-web_2.pdf*

is not always linked to their properties or biological activities, but rather to their image and stories. For example, oils from exotic fruits, nuts or grains are usually not directly linked to the purpose of the product – for example, cleansing or moisturizing – but are highlighted because of the marketing appeal of their origin or uses in traditional beauty rituals.

Investments and approaches to R&D vary enormously within the cosmetics sector. Some companies minimally process raw materials to produce simple products for local sale or process plants into well-known extracts or essential oils. Others – particularly specialized laboratories and multinational brands – undertake advanced research on new ingredients which may involve screening material, extracting active ingredients and undertaking safety, quality or effectiveness tests.[63] Recent innovations include active ingredients for skin care developed on the basis of plants used in the Ayurvedic tradition and extracts taken from algae cells grown in laboratories.[64]

Cosmetics companies generally look to source natural ingredients – whether for research, development or commercialization – from established, reliable supply chains, which are mostly cultivated.[65] Wild collection continues when there is specific interest or demand related to better quality, lower prices or species new to the market or used in small quantities. Traditional knowledge may be used in R&D, though primarily as part of broader literature studies rather than through new field investigation.[66]

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

Modern traditional cosmetic products in Jamaica.

[63] See Wynberg and Laird, Bioscience at a Crossroads: The Cosmetics Sector, supra note 61.
[64] The best ingredients: in-cosmetics Innovation Zone Award Winners announced. *Cosmetics & Toiletries Magazine,* April 13, 2016; available at: *www.cosmeticsandtoiletries.com/networking/news/company/The-Best-Ingredients-in-cosmetics-Innovation-Zone-Award-Winners-Announced-375575041.html#sthash.O9QnucQL.dpuf*
[65] See Wynberg and Laird, Bioscience at a Crossroads: The Cosmetics Sector, supra note 61.
[66] Ibid

IP considerations

Historically, IP within the cosmetics and personal care industry – and particularly in flavors and fragrances – was protected by keeping formulations confidential,[67] and trade secrets remain the most widespread means of protecting the intangible assets that are produced through day-to-day innovation in the sector. This is possible because the U.S., the European Union and other countries make certain exceptions to rules that generally require cosmetic and personal care products include a list of all ingredients. For example, in the U.S., fragrance and flavor ingredients do not need to be listed individually on cosmetic labels because they are the ingredients most likely to be "trade secrets". Instead, they may be listed simply as "fragrance" or "flavors". Similarly, in the European Union perfume mixtures, with a few exceptions, can be labeled collectively as "parfum". The rationale for these exceptions is that fragrance and flavors formulas are complex mixtures of many different natural and man-made chemical ingredients, and they are the kinds of cosmetic components considered to be trade secrets.

Given that cosmetics and personal care companies place such great value on confidentiality and trade secrets, negotiations of mutually agreed terms may require particularly stringent confidentiality clauses or parallel non-disclosure agreements. Box 25 provides an example of non-disclosure provisions used in a collaboration contract in the cosmetics sector.

In recent decades, however, companies have increasingly sought to protect inventions through patents. Studies show rising patenting activity in the sector over the past 20 years.[68] Activity is concentrated in cosmetics, notably skin care and hair products, but patenting linked to fragrances constitutes an emerging area. A high proportion of patent activity for cosmetics involves ingredients and extracts of natural origin: ingredients and extracts from all natural sources accounted for 49 percent of all patent activity in the personal care industry between 1990 and 2009.[69] During that time, ingredients and extracts from plants ac-

[67] International Fragrance Association (IFRA) (2013). *Valuable Yet Vulnerable: Trade Secrets in the Fragrance Industry.* IFRA, Geneva, Switzerland; available at: *www.ifraorg.org/view_document.aspx?docId=23107*

[68] UEBT (2010). *Trends in Patent Activity in the Cosmetics and Perfume Sectors: A Review of Patent Activity in the Cosmetics Sector in the Context of the Ethical Sourcing of Biodiversity.* UEBT; Geneva, Switzerland; available at: *http://ethicalbiotrade.org/dl/public-and-outreach/UEBT%20Trends%20Patents%20Activity%20Note%201%20of%204.pdf* Between 1990 and January 2010, 190,287 patent publications for cosmetics and perfumes were published in the major patent offices, rising to 329,983 publications worldwide.

[69] Ibid.

counted for approximately 34 percent of patent activity.[70] However, as in other sectors, there seems to be a growing use of defensive patenting strategies in the cosmetics and perfumes sector. In other words, more and more patents are sought not necessarily with a view to exploitation, but rather to secure their competitive position and prevent further R&D on a particular formulation or process.

Box 25: Sample clause on non-disclosure used in the cosmetics sector

"Except mutually and expressly agreed by the parties, each party hereby respectively undertakes not to:

- disclose or communicate to any third party the context of the agreement and supporting documents, whatever the nature, form or support of such disclosure of communication;
- use the agreement or supporting documents for any other purpose than complying with obligations under the agreement; and
- reveal the content and existence of this agreement.

Likewise, the parties hereby agree to keep secret any and all information and data exchanged during the negotiations of the agreement, whatever the nature, form or support of such information and data."

Collaboration agreement involving companies in the cosmetic sector.

Though patent activity in the cosmetics sector is still much smaller than in industries such as pharmaceuticals and industrial biotechnology, it is expected to increase further in line with the growing interface between different sectors and the use of novel technologies. For example, the use of nanotechnology in cosmetics is not new – nanoscale particles of titanium dioxide and zinc oxide have been used in sunscreens for many years – but surveys show that almost all the major cosmetic manufacturers now also use this technology in other products.[71] Trends in advanced research in cosmetics also point to the increasing use of biotechnology-

[70] Of course, patent data do not necessarily speak to the actual economic value of patented methods and products.

[71] S. Raj, S. Jose, U.S. Sumod and M. Sabitha (2012). Nanotechnology in cosmetics: opportunities and challenges. *Journal of Pharmacy & BioAllied Sciences,* 4(3), 186-193; available at: *https://www.ncbi. nlm. nih.gov/pmc/articles/PMC3425166/*

derived ingredients. In this context, issues linked to patents, licensing and royalties will also become more relevant in negotiations of mutually agreed terms that involve the cosmetics and personal care sector.

Food and beverages

Plants and animals are the basis of the world's food supply; but the utilization of genetic resources within the food and beverage sector is much more limited.[72] Many activities pertaining to the supply, consumption and catering of food and beverage products – for instance, trade in raw material and processing of fresh products into canned and packed goods – do not involve R&D. Moreover, the food and beverages sector relies heavily on commodities such as palm oil, wheat or coffee, and new products mostly involve process improvements or slight variations on known ingredients for marketing purposes.

Nevertheless, R&D is significant in subsectors focused on specialty ingredients, such as functional foods (foods with a positive effect on health beyond basic nutrition) and nutraceuticals (bioactive compounds that are found in foods as well as in dietary supplements and herbal products). Sometimes, these ingredients are referred to as "botanicals" (see Box 26). Growing interest is, in part, due to market demand: consumer calls for healthy food and beverages continue to grow. Biodiversity-based products are also often used for their novelty and marketing value. Moreover, new technologies also facilitate innovation, including manufacturing processes based on membrane technology, super-critical fluid technology, encapsulation technologies and new thermal preservation techniques. The specialty food ingredients market was valued at USD 66.4 billion in 2014 and projected to grow 5.5 percent per year from 2015 to 2020.[73]

[72] R. Wynberg (2013). *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Food and Beverage Sector.* Secretariat of the Convention on Biological Diversity, Montreal, Canada; available at: *https://www.cbd.int/abs/doc/protocol/factsheets/policy/abs-policy-brief-Food-web.pdf*

[73] Markets & Markets (2016). *Specialty Food Ingredients Market by Ingredient and by Application – Global Trends and Forecast to 2020;* available at: *www.marketsandmarkets.com/Market-Reports/speciality-food-ingredients-market-252775011.html*

Box 26: Botanicals

Botanicals is a term used to refer to plant-based ingredients or products primarily used as medicines or to promote health and well-being more broadly. Botanicals are sold as single ingredients or mixtures, and go into herbal medicines, dietary supplements, cosmetics, sports drinks, functional foods and other food and beverages (e.g., as natural colourings, flavorings and preservatives).

Traditional knowledge is the primary guide to new ingredient and product development in botanicals; it is integral to acquiring approval from regulatory agencies and is used in marketing products to consumers. Although novel ingredients and products are of real interest to the industry, in recent years this interest has decreased. In many regions, government oversight of the safety, efficacy, purity and quality of products has increased, requiring more expensive and timeconsuming testing than before.

Photo: © Hartmut Meyer/ABS Capacity Development Initiative

Modern traditional food products in Jamaica.

The Jamaica-made mark programme is a voluntary conformity assessment programme that relies on the use of certification marks. A certification marks is a special type of trademark which indicates that the goods or services in connection with which it is used are certified by the owner of the mark as being compliant with certain standards, which may include, for example, geographical origin, material, mode of manufacture of goods, quality, or other characteristics. A certification mark can be used by anyone who complies with the standards defined by the owner of the certification mark. The Jamaica-made mark serves to create a competitive advantage for authentic Jamaican products, strengthen consumer confidence in the authenticity and quality of Jamaican products locally and internationally and provide economic benefits to local manufacturers.

Approaches and trends in the utilization of genetic resources

The pace of R&D in specialty ingredients is rapid, since health remains one of the main innovation drivers. For example, the number of launches of food products that contain selected "superfruits" doubled between 2008 and 2012.[74] These superfruits include well-known names such as blackberries and grapes, as well as so-called "exotic fruits" such as acai, baobab, noni, goji and camu-camu.

Elaborating new food and beverage specialty ingredients often involves R&D. Scientists and companies look at the chemical composition of plant or other genetic resources to learn how their constituents benefit human health, both individually and in combination. For example, camu-camu (*Myrciaria dubia*) has a multitude of nutrients, including vitamins, minerals, flavonoids, amino acids, protein and fiber – it is considered the most potent plant source of vitamin C in the world.[75] Camu-camu and other fruits and plants are also assessed for additional properties that may allow their use in food supplements or other products. There also tend to be evaluations of safety and toxicity required by laws and regulations.

[74] L. Williams (2013). *Supply and Demand Trends in the Global Superfruits Market*, presentation at the International Symposium on "Superfruits: Myth or Truth?"; available at: *www.itfnet.org/Download/Superfruit2013/Main_Session_2/WILLIAMS_Supply_and_demand_trends_in_the_global_superfruits_market.pdf*

[75] See, e.g., P.C. Langley, J.V. Pergolizzi, R. Taylor and C. Ridgway (2015). Antioxidant and associated capacities of Camu (Myrciaria dubia): a systematic review. *Journal of Alternative and Complementary Medicine* 21(1), 8–14; available at: *http://doi.org/10.1089/acm.2014.0130*

Traditional knowledge often points researchers to interesting ingredients for food and beverages. Furthermore, traditional knowledge may be used to facilitate evaluations of safety and efficacy required for such ingredients. For example, under the revised Novel Food Regulation issued in the European Union in 2015, if a proposed "new" food ingredient is traditional and can be demonstrated to have been safe historically, it will not require a full assessment, but rather a notification from the food business operator.[76]

Photos: © Lena Fey/ABS Capacity Development Initiative

Production of functional foods by Djeka Pharmaco, Côte d'Ivoire.

The Ivorian enterprise Djeka Pharmaco adds herbal extracts to sugar and salt for positive health effects. The combination of herbs used in these products is based on the traditional knowledge of Ivorian healers. Djeka Pharmaco's products were successfully tested for non-toxicity and efficacy, and are recommended by the West African Health Organization (WAHO). The Ivorian government actively promotes traditional medicine and currently supports the enterprise in its efforts to obtain patent protection for its products.

[76] European Commission (2015). "Questions and Answers: New Regulation on Novel Food" factsheet; available at: http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm

IP considerations

With increasing focus on research and development R&D, subsectors focused on specialty ingredients are also increasingly turning to patents to protect their innovation. Research in these subsectors is competitive and intense. For example, patents related to probiotics (live microorganisms added to food) grew from 400 patent records per year in the 1970s to 1,200 patents published in 2010.[77] Indeed, between 25 percent and 30 percent of patents in the food sector are related to functional foods.[78] This is noteworthy, given that this sector is not widely known for its innovation activities and providers may not always foresee relevant patent-related provisions in mutually agreed terms.

Another issue that may be considered in mutually agreed terms for the utilization of genetic resources in the food and beverage sector is possible exclusive rights over health or nutrition claims made in relation to functional foods. Nutrition claims describe the level of a nutrient in a food product using terms such as “free”, “high” and “low”. Health claims describe a relationship between a component or ingredient of food and beverage products and the reduced risk of disease or health-related conditions. Under some legislation, an applicant for authorization for a health or nutrition claim enjoys a period of exclusivity in relation to the data it discloses in support of the application. For example, European Union Regulation (EC) No. 1924/2006 includes provisions on data protection under which a company that has identified nutrition or health claims for food products has the exclusive right to rely on its proprietary data in support of the authorization of such claims for a period of seven years.

[77] Gridlogics (2011). *Technology Insight Report: Probiotics;* available at: *www.patentinsightpro.com/techreports/1011/Technology%20Insight%20Report%20-%20Probiotics.pdf*

[78] Clarke, Modet & Co. (2010). Intellectual Property in the Area of Functional Foods; available at: *www.clarkemodet.com/en/news/blog/2010/11/Intellectual-Property-in-the-area-of-Functional-Foods#.WDgra-ErJE4*

Concluding summary

International instruments including the CBD, the Nagoya Protocol and the ITPGRFA have recognized not only that IP-related issues arise in the context of ABS, but also that properly framing and addressing these issues may be critical in advancing fair and equitable ABS negotiations and agreements.

As established by the CBD, the ABS system is largely based on terms and conditions being mutually agreed by providers and users, including on permitted utilization of genetic resources, obligations for users and providers, transfer to third parties, treatment of confidential information and provisions regarding the sharing of benefits.

Decisions on whether and how to secure and manage IP rights may significantly impact on such terms. For example, inventions based on or derived from genetic resources may be patentable or subject to other forms of IP rights. Understanding the precise rationale and extent of requests for confidentiality is essential to arrive at practical and effective solutions.

Another example explored in this guide is patent licensing. Mutually agreed terms may include the sharing of benefits linked to patent licenses. In such cases, it becomes important to understand the most likely approach to such licensing and the possible payment structure for any rates and other fees.

Of course, the relevance of patents and patent licensing will depend on the proposed research, development and commercialization activities. Indeed, as this guide has shown, different industries using biodiversity as a source of inputs and ingredients work with different types of genetic resources, access these resources in different ways and through different types of actors, and use the resulting information and innovation in different ways to develop products and processes. Particular sectors such as pharmaceuticals, biotechnology, agriculture, cosmetics, and food and beverages are therefore likely to require rather different IP provisions in mutually agreed terms.

Subject to applicable laws, it will be for the parties negotiating mutually agreed terms to agree their preferred approach in each case, and nothing in this guide should be seen as presuming to dictate parties' choice of terms – or, indeed, whether to reach an agreement on access at all.

But by providing an overview of the types of IP-related issues that arise in mutually agreed terms and the options for managing them, this guide should help ensure that both providers and users can negotiate on an informed basis. In so doing, it will hopefully also help to promote fair and equitable benefit-sharing and the conservation and sustainable use of biodiversity.

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