

Genetic Resources From Biodiversity: Reflections On Contractualization In The Light Of The Latest News

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Summary:

Currently, a major issue arises regarding the use and the exploitation of genetic resources issued from countries owning such resources by exploiting parties, due to the lack of balance regarding the access and benefit sharing (ABS) from such acts.

In order to ensure a fair benefit sharing due to these resources and prevent biopiracy matters, the Convention on Biological Diversity (CBD) (1992) and the Nagoya Protocol (1996) are major legal instruments relating to access and sharing of genetic resources and their associated traditional knowledge, which would be used and exploited by exploiting parties. However, these texts lack key notions concerning any general rules for the use and the exploitation of genetic resources in scientific publications and/or R&D programs, but also regarding the creation of innovative products, notably by startups but also major companies, thus leading to uncertainty in the fair application of the ABS principles.

In this respect, the users of genetic resources need some clarifications regarding the proceedings in order to obtain the authorizations from the providers in this matter and to ensure the proper contractualization to access an important raw material. Also, this point is important especially for securing startups in charge of investing in R&D programs and for exploiting results, either directly or through a technology transfer.

The purpose of this article is to present a global update on the latest trends in intergovernmental instruments to frame the use of resources not originally foreseen by the Convention on Biological Diversity or the Nagoya Protocol, while indicating some key questions on this matter.

Introduction:

Genetic resources from biodiversity and its valorization constitute a major challenge for the states providing the resources, but also for their users, such as universities, technology transfer offices and startups for realizing scientific studies, as well as the industry parties in charge of exploiting, particularly in health, cosmetics, chemistry and energy.

In the current society, there is a major issue between the South countries and the North countries about this

topic, as the majority of the biodiversity is located in the South countries and that the developed countries in the North have the overall economic resources for developing and exploiting innovations (directly or through technology transfer) using this biodiversity, especially the genetic resources.

Thus, its conservation and exploitation have become a common concern for both biodiversity-holding countries and users. Indeed, the economic and environmental stakes linked to biodiversity are communicated at length by the different media and political powers in place, so that many studies have been carried out in this field.

However, it is important to note that there is a misunderstanding between preserving the global biodiversity, through a climate perspective, and using some samples from this biodiversity for new innovations profitable for mankind.

It is then important to find a balance between the interest of each side, namely:

- Allowing the open science and the exploitation of genetic resources, and;
- The need for fair benefit sharing of such exploitation and use and access control of genetic resources for the providers.

However, their access and use are now subject to procedures that are increasingly complex to implement. Generally, such genetic resources are not directly exploited, but it requires huge investments in R&D development, production and regulatory matters before obtaining and exploiting new products. There is also a risk for exploiting parties to be involved in biopiracy matters, and then to lose reputation.

Then, to define rules for using biodiversity, the Con-

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vention on Biological Diversity was adopted in Rio de Janeiro in 1992 and then entered into force on 29 December 1993.¹ It was supplemented by the Nagoya Protocol, adopted on 29 October 2010.² These international legal instruments aim to regulate access to genetic resources and to establish a fair and equitable sharing of the benefits arising from the use of these resources (ABS).³

These instruments provided key definitions regarding the ABS principles as applied to technology transfer and/or R&D studies based on genetic resources issued from biodiversity:

Some Key Definitions from Article 2 of the Convention on Biological Diversity:

- “Biotechnology” means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
- “Country of origin of genetic resources” means the country which possesses those genetic resources in *in-situ* conditions.
- “Country providing genetic resources” means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.
- “Domesticated or cultivated species” means species in which the evolutionary process has been influenced by humans to meet their needs.
- “Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity.
- “Genetic resources” means genetic material of actual or potential value.
- “Technology” includes biotechnology.

Complementary Key Definition from Article 2 of Nagoya 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 Convention.
- “Derivative” means 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.

However, some major actors concerned by the legal framework of the ABS principles were not currently precisely defined, such as mainly “Provider” and “User” of genetic resources. This lack of definitions would lead to challenges in interpreting the Convention on Biological Diversity. Concerning “derivative,” its definition provides ambiguity in its interpretation.

For the purpose of this article, the following definitions will be indicated:

- The Provider is an entity wishing to transfer genetic resources. It can be the providing country directly, suppliers of resources such as private or academic institutes, universities or landowners, but also *ex-situ* collections;
- The User is considered as the entity wishing to access genetic resources. It can represent, respectively, various actors, *e.g.*, the bioprospectors, research institutes, universities, *ex-situ* collections, R&D or industrial companies.⁴

Even by defining these actors, many questions arise regarding the procedures to be followed in order to be able to access and use a specific genetic resource (whether it is of terrestrial or marine origin, or even from a digitized collection) and the associated traditional knowledge. Questions deserve to be raised with regard to the sharing of benefits that will be negotiated, taking into account, from the perspective of this article, the considerations regarding technology transfer, which involves questions of intellectual property.

Some Issues Relating to Contractualization Involving Genetic Resources for Developing, Protecting and Exploiting Technologies From Such Resources

In the context of the implementation of access and benefit-sharing agreements, as advocated by the Nagoya Protocol, intellectual property issues around the use of genetic resources and/or traditional knowledge by innovative companies must be raised upstream in order to ensure strategic management that benefits each party in the system downstream.

In any R&D program associated with the use of genetic resources, authorization is required before initiating such a program. However, due to the characteristics of such a program, the planned results may not be the concrete ones. Sometimes, the results would differ from the expected ones, but could then be exploitable.

While the results of an R&D program may be uncertain and unknown for the parties, it is necessary to define upstream the main lines related to the means of protection of the results, as well as those associat-

1. Convention on Biological Diversity. 1992. <https://www.cbd.int/convention/text>.

2. Nagoya Protocol. 1996: <https://www.cbd.int/abs/text/>.

3. The ABS Mechanism—What is ABS? s.d. <https://www.abs-biotrade.info/topics/the-abs-mechanism/what-is-abs/>.

4. Tichet, Camille; Nguyen, Hong Khanh; El Yaakoubi, Sefia; Bloch, Jean-François (2010). “Commercial product exploitation from marine microbial biodiversity: some legal and IP issues.” *Microbial Biotechnology, Special Issue: Volume 3, Issue 5*, sept 2010 (507-513).

ed with the exploitation of these results. It could be possible, in some cases, that a complementary transfer agreement has to be defined between the final commercial exploiting party of the genetic resources and the User that has led the R&D studies, notably if the commercial party is not the one that conducted the studies. Any amendments of the agreement between the R&D partner and the final User could then have an impact regarding the Provider.

From the point of view of protection and exploitation of R&D results, the following figure summarizes the general ABS principles based on the CBD and Nagoya Protocol and some key questions to be considered by the User. See Figure 1.

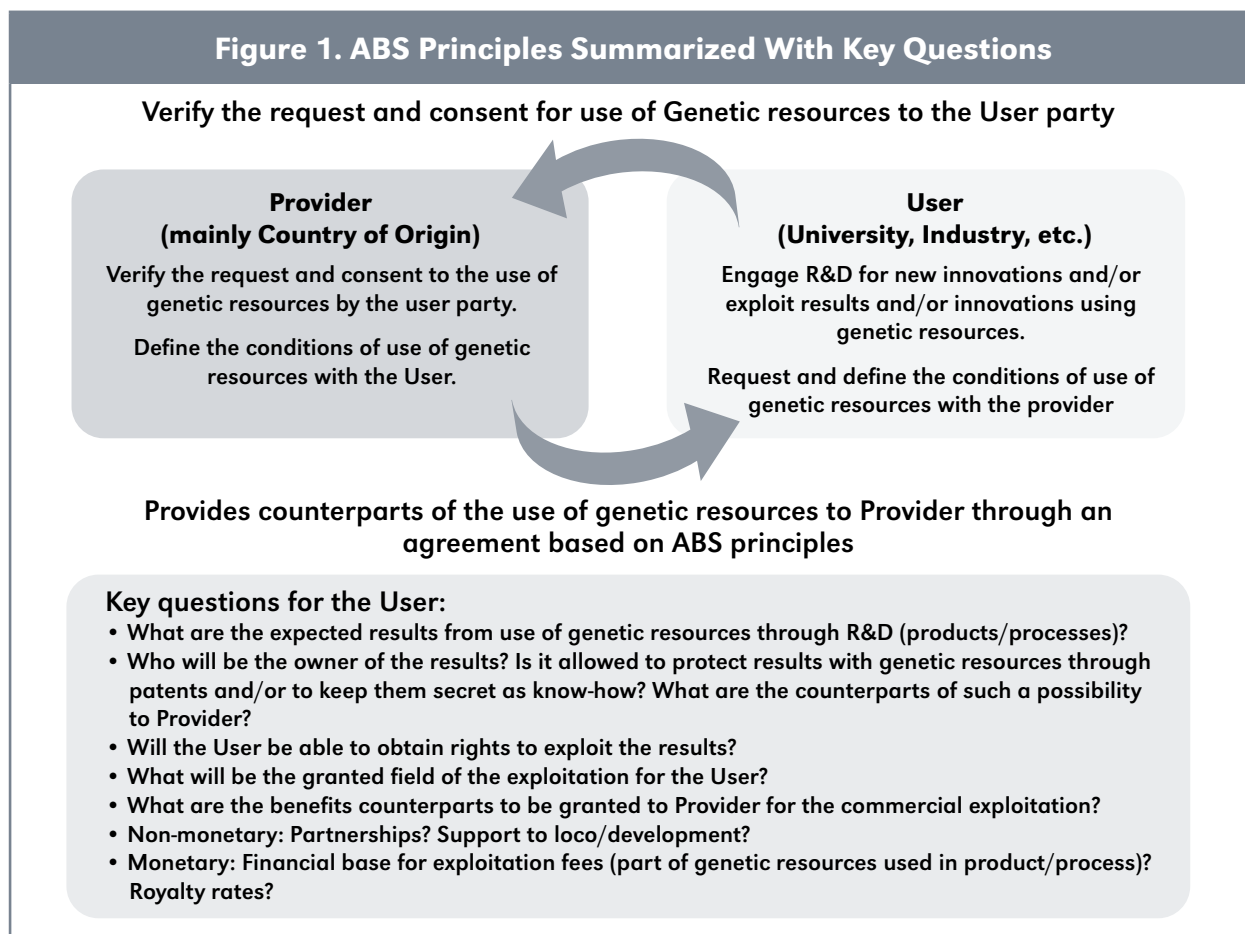
Due to the fact that each Member State of the CBD and Nagoya Protocol has different rules regarding the ABS principles, it is currently challenging for the User to find a “template” for defining the mutual agreement for the use and exploitation of genetic resources:

–Some countries, such as Brazil, have defined a strict and rigorous ABS policy in order to prevent massive bioprospecting for developing new innovations and to check the relevant use of its genetic resources (obligation to disclose the origin of genetic resources in patent application).⁵

–In France, there are some exceptions regarding the implementation of ABS policies for some resources:

- For some specific genetic resources managed by the Ministry of Agriculture (notably genetic resources from domesticated animal species, genetic resources of cultivated and wild relatives of plants, and genetic resources of domesticated and cultivated micro-organism species), it was decided not to implement the Nagoya Protocol principles for such resources.⁶
- Some other microorganisms used as models for R&D purposes, under French sovereignty, would also be excluded from the ABS principles, accord-

Figure 1. ABS Principles Summarized With Key Questions



5. Brazilian Law No. 13,123, of May 20, 2015, relating to access to genetic heritage and associated traditional knowledge and regulates benefit sharing: <https://www.wipo.int/wipolex/en/text/490992>.

6. “Ressources génétiques : l’application du protocole de Nagoya en France,” French Ministry of Agriculture, last modified May 12, 2023: <https://agriculture.gouv.fr/ressources-genetiques-lapplication-du-protocole-de-nagoya-en-france>.

ing to Article L412-5 of the French Environment Code.⁷ Once the concerned microorganisms are listed, the User would then be free to use and exploit such genetic resources.

Regarding the different elements above and based on our practice, it appears that startups are often involved in R&D programs based on genetic resources and mainly have the responsibility of fulfilling ABS principles. The universities are mainly involved in the R&D aspects, whereas exploiting parties request warranties in exploitation agreements.

However, ABS principles must be proposed at the time the application is drawn up, which means that the valuation rules must be known in advance before any innovative projects associated with such genetic resources can be launched. This imposes a high level of knowledge of the potential value generated by the R&D project. However, there is always some uncertainty as to the expected economic potential. It is therefore difficult to be sure of the existence or amount of revenue that can be generated from a genetic resource.

Actually, startups do not usually have the capacity to anticipate and ensure the exploitation of results and the fulfillment of conditions from ABS agreements (conditions of use, benefit sharing, etc.), mainly because of uncertainty of the R&D results, and the to-be defined conditions of the exploitation of results. Because of such uncertainties, this would not then be supportive of the emergence of startups that would become major actors in innovations using genetic resources.

In order to prevent this matter, ABS principles could be more flexible for Users, in order to allow them to implement these principles in their development projects, given that unsuccessful negotiations of ABS conditions could block the R&D aspects of the projects, and then hinder innovation and partnership projects for the exploitation of results stemming from the used genetic resources.

Whereas major companies can provide non-financial advantages for Providers, such as partnership or involvement in local development, it would be difficult for startups to provide such advantages as they would mainly financially invest in R&D programs.

Moreover, startups are mainly the Users that need information and advice to help them understand the different genetic resource regimes, and then take the necessary steps to comply with the regulations in force

for any innovative projects (R&D studies, exploitation of results). Negotiating the ABS conditions should then be defined in accordance with companies' current R&D and commercial capacity, but also financial investments intended for any project involving genetic resources and the associated traditional knowledge.

Some Practical Tips in Light of the Constraints of ABS Mechanisms and Future Intergovernmental Instruments Governing the Use of Non-territorial Resources

In light of the above, it appears that the definition of a contract upstream, although important, risks complicating the procedures to be followed for commercial exploitation due to different origins of genetic resources (marine, digital, etc.).

Indeed, for example, from the point of view of patent protection, some states require that the IP office verify the existence of prior authorization for the use of the genetic resource that is the subject of the patent, in particular by checking the content of the associated agreement, which appears to contradict the principles linked to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which does not require such verification.⁸

For example, in India, Section 6 of the *National Biological Diversity Act of 2002* indicates that “no person shall apply for any intellectual property right, (...) for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application.” Regarding any patent applications, “permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.”⁹

This illustrates a divergence on the importance of preserving biodiversity with regard to climate and human issues and the role of intellectual property as a commercial instrument allowing a company to have a competitive advantage in its operating market.

At the time of the article, the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) is currently discussing the matter, “with the objective of finalizing an agreement on an international legal instrument(s), [...] relating to intellectual property which will ensure the balanced and effective protection of genetic resources, traditional knowledge and traditional cultural expressions.”

7. Article L.412-5 d) of the French Environment Code: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000044233732. This article indicates that among the resources not concerned by the French ABS principles, are “Genetic resources of species used as models in research and development. A joint order of the ministers responsible for the environment, agriculture, research, health and defense indicates the list of these model species.” Such list is currently under development at the time of the article.

8. Roca, Santiago. (2021). “Compatibility of the Intellectual Property Regime, the Convention on Biological Diversity and the Nagoya Protocol.” *GRUR International*. 70. 10.1093/grurint/ikaa182.

9. English version of the Indian Biological Diversity Act 2002: https://nbaindia.org/uploaded/act/BDACT_ENG.pdf.

Through this finality, in July 2022, the WIPO General Assembly decided to convene a Diplomatic Conference to conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources. A Preparatory Committee on the Diplomatic Conference will take place from 11 to 13 September 2023, in order to prepare such an instrument. It could be based on the IGC Chair's text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated With Genetic Resources, produced on 30 April 2019, whose goals would consist of enhancing the efficacy, transparency and quality of the patent system with regard to genetic resources and the associated traditional knowledge and preventing patents from being granted erroneously for inventions that are not novel or inventive with regard to such resources and knowledge.¹⁰

This reflection should also take into account the "Treaty of the High Seas" concluded on 5 March 2023 by the delegates of the Intergovernmental Conference on Marine Biodiversity beyond National Jurisdiction (BBNJ), and signed on 19 June 2023 by the United Nations.¹¹ Among other things, this treaty aims to incorporate a mechanism for the fair and equitable sharing of benefits arising from marine genetic resources and to contribute to the generation of knowledge, scientific understanding and technical innovation.¹²

The issue of the exploitation of digitally sequenced resources should also not be overlooked. At the end of the Conference of the Parties to the Convention on Biological Diversity, which took place from 7 to 19 December 2022 in Montréal, a draft decision was proposed by the President, which concerns digital sequencing information on genetic resources in order to try to establish a multilateral system for benefit-sharing from such assets. This draft decision indicates, among other things, the commitments by contracting parties to transpose the ABS mechanisms related to digital sequencing informa-

tion on genetic resources through taking "effective legal, policy, administrative and capacity-building measures at all levels, as appropriate, to ensure the fair and equitable sharing of benefits that arise from the utilization of genetic resources and from digital sequence information on genetic resources, as well as traditional knowledge associated with genetic resources, and facilitating appropriate access to genetic resources, and by 2030 facilitating a significant increase of the benefits shared, in accordance with applicable international access and benefit-sharing instruments."¹³ Beyond the principles indicated in this project, for a fair ABS between North countries and South ones, difficulties in implementation will arise due to the lack of precise rules that the contracting parties will have to follow.

Although the latest developments in legal instruments in this area may provide some answers, there are still some unanswered questions relating to the legally secured exploitation of genetic resources and their associated traditional knowledge in relation to the ABS principles. There are still some administrative issues concerning the management of ABS principles by Users, as this is time-consuming, especially for startups. Besides, such uncertainties remain challenging for investing in R&D in this domain, as this could discourage potential investors for Users in financing such programs.

Thus, while waiting for the implementation of these future legal instruments, the Users that envisage the development of new technologies or innovations involving genetic resources, without being accused of biopiracy, will have to take the following steps before any use of these resources and their associated traditional knowledge:

- Obtain information from the Provider state on its own conditions of use and exploitation of the resource and/or associated knowledge.
- Carry out a study of the prior art associated with this resource, in case of a possible patent project involving this resource.
- Negotiate upstream an agreement for the use and exploitation of the resource, taking into account the final innovation that will be commercialized, while trying to obtain the maximum possible guarantees on the possibility of using the resource (either from the Provider, or from the university/major industrial company if the User/exploiting party is a startup). ■

Acknowledgements

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10. WIPO/GRTKF/IC/43/5: Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated With Genetic Resources: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=572391.

11. United Nations—UN News. Beyond borders: Why new 'high seas' treaty is critical for the world. June 19, 2023. <https://news.un.org/en/story/2023/06/1137857> (accessed June 29, 2023).

12. Draft agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. June 12, 2023. https://documents-dds-ny.un.org/doc/UNDOC/LTD/N23/073/63/PDF/N2307363.pdf?OpenElement=&_gl=1*e2ehnb*_ga*MjAwMTM5NDI3OS4xNjg4MDO4MDk4*_ga_TK9BQL5X7Z*MTY4ODA0ODA5Ny4xLjEuMTY4ODA0ODI0OS4wLjAuMA (accessed June 29, 2023).

13. Kunming-Montreal Global biodiversity framework—Draft decision submitted by the President. Fifteenth meeting—Part II—CBD/COP/15/L.25—18 December 2022: <https://www.cbd.int/doc/c/e6d3/cd1d/daf663719a03902a9b116c34/cop-15-l-25-en.pdf>.