

## Genetic Resources and Property Rights. Tangible and Intangible Property Rights. The Issue of Derivatives.

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### The International Regime on Access and Benefit-sharing (IR-ABS)

On the whole, the negotiation of an International Regime on Access and Benefit-sharing (IR-ABS) offers the opportunity to agree upon a multilateral frame of rules and procedures to promote and to safeguard the fair and equitable distribution of benefits arising out of the utilization of genetic resources and its derivatives, as well as of the knowledge, innovations and practices of indigenous and local communities for the conservation and sustainable use of genetic resources and derivatives.

These rules and their mechanism of compliance and enforcement would have to be complemented by legislative, administrative or policy measures among developed country Parties, a system of incentives for both providers and users, a mechanism of transference of technologies and know-how to developing country Parties, a financial mechanism, and other means that would facilitate the operation of the regime including a process of communication, education and public awareness.

### Property Rights, Genetic Resources and Derivatives

A clear distinction of rights and obligations of Contracting Parties that are *developing countries of origin of genetic resources and derivatives* from those other Parties that have acquired these resources in accordance with the Convention on Biological Diversity (CBD), is a critical condition for a successful IR-ABS.

For this distinction, profound implications arise at all levels, in particular concerning the rights, obligations, and expectations of local communities, authorities, suppliers, investigators and users of both genetic resources and their derivatives (GRD).

### Rights and Obligations of the Nation-State in Countries of Origin

Recent policy research in Colombia<sup>2</sup> has come to the conclusion that the rights of the country of origin of the GRD can be better understood by means of the following two concepts:

- The general interest as an attribute of the sovereign rights of States over their natural resources; and
- The genetic resources and derivatives as public patrimony of the Nation.

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<sup>1</sup> The views presented in the above text are those of the author and do not reflect the position of the government of Colombia in the negotiations on the International Regime on ABS.

<sup>2</sup> These notes are based in extracts of the project: "Policy of Access and Use of Genetic Resources in Colombia" proposed by the Alexander von Humboldt Institute.

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Accordingly, the authority of national governments to determine access to genetic resources, subject to national legislation, gives these authorities administrative property over GRD as well as the public role of creating conditions for their access, conservation and sustainable use.

Due to the States' responsibility as administrator of inalienable resources, national governments exercise the role of safekeeping and monitoring GRD as well as being held accountable for guaranteeing national sovereignty over these resources, along with the rights of the indigenous and local communities and associated traditional knowledge.

#### **Rights and Obligations of the Providers in Countries of Origin**

The government of the country of origin exerts rights as provider when that country is the direct supplier of the GRD. This situation arises from GRD that are located in public lands or lands that have been declared as protected areas, including in situ conservation efforts as well as ex situ collections under the State's administration. In all other cases, the supplier will be a third party. In such an event, it is necessary to define the rights and obligations under national laws of those who provide GRD, including local communities, research institutions, and ex situ collectors.

In Bolivia, Colombia, Ecuador, Peru and Venezuela, all members of the Andean Community, GRD are inalienable resources, that is to say, these resources are public property. Therefore, according to this legislation, genetic resources and their derivatives can neither be sold, nor bought. There are no private property rights over the tangible and intangible components of GRD.

Bearing in mind the Andean Community Law on access to genetic resources and derivatives<sup>3</sup>, all suppliers of GRD should have the following rights recognized:

- Rights of possession of the GRD, when there is complete evidence that the provider has been conserving the intrinsic value of biological diversity and the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of these resources;
- Rights of Prior Informed Consent (PIC) on the utilization of genetic resources and its derivatives in the case that the providers have been recognized a right of possession; and
- Rights to the benefits arising from the utilization of genetic resources and its derivatives in the case that the providers have been recognized a right of possession.

In all the above cases, the obligations of the supplier are to be supportive of, and not to be counter-productive to, GRD of a national interest and/or public patrimony of the nation. Furthermore, providers should not contravene any of the stipulations of Andean Decision 391.

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<sup>3</sup> Decision 391 of 1996 regulates access to genetic resources and derivatives, and Decision 486 of 2000 regulates industrial property.

### **Rights and Obligations of Providers/Users from Parties that have Acquired GRD in Accordance with the CBD**

According to numerous research papers and other references,<sup>4</sup> providers are converted into users when applicants wanting to access GRD have been granted legal authorization by national authorities from the country of origin. This is to say that providers from Parties that have acquired GRD in accordance with the CBD, fall in the category of applicants for the effects of national ABS regulation. This type of 'second floor' provider includes ex- situ gene banks, located inside and outside the country of origin, or any other collector or researcher that has previously obtained access to GRD from an in situ supplier in a country of origin.

The applicant for authorization to use GRD acquires, by means of a contract with the country of origin, a set of rights and obligations that do not include ownership over these resources or their inherent information.

On the side of the country of origin, national authorities should recognize that the applicant/user/provider from a country different from the country of origin is given the following rights:

- The right to use GRD under conditions and obligations mutually decided upon by the national authority and the applicant. This use does not cover the transference or acquisition of the property of these resources, because they are public property and therefore non-transferable. The applicant will neither be able to transfer the property of such resources to a third party. In addition, the user cannot change the agreed end-use of GRD without the permission of the authorities of the country of origin;
- The right to claim immaterial property<sup>5</sup> on the developments that are obtained from the use of the GRD and the value which the developer or inventor adds to such resources (subject to intellectual property rights). This can include knowledge or information on resources, including new products or processes technologies, methodologies or services; and
- The right to be informed by the national authorities from the country of origin - in a clear, transparent and opportune way - about the conditions and terms in which access to GRD will take place.

According to the Andean Community<sup>6</sup>, however, the competent national authority may, either ex officio or at the request of a party, and at any time, declare a patent null and void, if:

- The products or processes related to the patent which is being filed have been obtained and developed on the basis of genetic resources or their derivatives

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<sup>4</sup> A number of these research and policy papers are cited or referred to at: [www.biodiv.org](http://www.biodiv.org)

<sup>5</sup> Here we are referring to patents and other intellectual property rights that allow a "down stream" user a monopolistic right for a limited amount of time on immaterial products of intellectual nature and of creative content, by virtue of, the exercise of the holder of the right.

<sup>6</sup> Decision 486, 2000, Article 75.

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originating in one of the Member Countries, and if the applicant failed to submit a copy of the contract for access to that genetic material; and

- The products or processes whose protection is being requested have been obtained or developed using traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, and if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the Member Countries.

On the user country's side, "each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights".<sup>7</sup>

For transparency and accountability reasons, the legal authorization to use GRD, that is, a copy of the contract for access (if the products or processes for which any patent application are being filed were obtained or developed from genetic resources or derivatives of countries of origin), should be placed in the CBD Clearing-House Mechanism.

If applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous and local communities should be available as well in the CHM.

### Property Rights on Tangibles and Intangibles

#### *Material or immaterial property?*

Addressing the issue of the tangible component of GRD involves recognition that in situ genetic resources and their derivatives refer to any living thing, either complete or partial, as found in nature, which means all natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing.<sup>8</sup>

One of the problems that hinder the question of bioproperty, and indeed the false distinction between tangible and intangible features of genes and molecules, is the absence of an adequate definition of genetic programs and their intrinsic relationship to genes, proteins, cell types, and other features of biological organisms including any plant, animal or microorganism containing functional units of heredity.

As stated above, the Andean Community considers GRD as inalienable, that is, they are public part of the patrimony of the developing country of origin. Access granted for specific uses of GRD do not include the property of these resources or their inherent genetic information (genetic programs).

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<sup>7</sup> CBD, Article 18.

<sup>8</sup> Decision 486, 2000, Article 15.

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In practice, concerns regarding the distinction between tangible genetic resources and intangible genetic programs have already been expressed within different international agreements such as The FAO International Treaty on Genetic Resources for Food and Agriculture, The Bonn Guidelines and the Andean Legislation. In all of these instruments, there is language that prohibits, or at least questions, the reclamation of intellectual property rights on genetic materials and genetic programs found in nature.<sup>9</sup>

*Intangible or immaterial property*

Immaterial property over knowledge and innovations is well accepted within Member Countries of the TRIPS Agreement and the Andean Community.<sup>10</sup> Within these agreements, patents are granted for inventions, whether goods or processes, and all areas of technology that are new, involve an inventive step, or are commercially applicable.

International rule-making institutions such as the World Trade Organization (WTO) set a range of obligations that protect intellectual property related to the knowledge, techniques and technologies that modify, transform and add value to the GRD.

Nevertheless, without adequate infrastructure, know-how and training, developing countries of origin are not protected from technology investors that do not contribute "to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".<sup>11</sup>

Actually, the mere protection of ideas<sup>12</sup> is not as important as recognizing that both access to and transfer of biotechnology from developed to developing countries (which are the providers of GRD) are essential elements for the attainment of the objectives of the CBD.<sup>13</sup>

*Limitations on access*<sup>14</sup>

The Andean Community may establish, through an express legal ruling, partial or total limitations on access to GRD in the following cases:

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<sup>9</sup> Annex B of the Bonn Guidelines of 2002; Article 12 of the International Treaty of Genetic Resources for Food and Agriculture (2002); Andean Decision 486 of 2000.

<sup>10</sup> Decision 486, Article 14.

<sup>11</sup> TRIPS Agreement, Article 7.

<sup>12</sup> It would be worth the trouble to consider the arguments of the economists Michele Boldrin and David Levine when they propose that the society does not have to recognize property rights on ideas and would only have to do it in the case of physical or tangible objects. To see: Boldrin, Michele, and David Levine. 2003. "The CASE against Intellectual Monopoly" Californian University of Los Angeles, draft book manuscript. First two chapters download from <http://www.dklevine.com/>

<sup>13</sup> CBD, Article 16.1 and 16.3

<sup>14</sup> Decision 391, Article 45.

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- Endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;
- Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access-related activities;
- Adverse effects of access-related activities on human health or on elements essential to the cultural identity of nations;
- Undesirable or not easily controlled environmental effects of access related activities on the ecosystems;
- Risk of genetic erosion caused by access related activities;
- Regulations on biosafety; or
- GRD or geographic areas rated as strategic.

*Collective property over ancestral genetic resources and derivatives*

Because of the fundamental role of GRD with added ancestral (cultural) value, the Andean countries recognize the historic contribution to biological diversity made by indigenous and local communities, through its conservation and development, the sustainable use of its components, and the benefits generated by such use.

The recognition of traditional values and uses implies an attempt to exclude from Andean legislation the exchange of genetic resources, derivatives and associated traditional knowledge for their own personal use, based on their own customary practices.

Furthermore, in the case of domesticated or transformed genetic resources and derivatives, the rights over these resources, when traditional knowledge is involved, are seen to belong to indigenous and local communities - including the selection or improvement of GRD by traditional techniques, and those that have been conserved, used and developed in a time and specific cultural space.

*Scientific research*

If GRD have an added value as a product or process of scientific research, the intangible or immaterial property of these results belong to the inventor or innovator. When this value is added in the country of origin, it should not be appropriated by users from other countries. The competent national authority may declare a patent null and void, if intellectual property rights over innovations generated in the country of origin are claimed, since information related to GRD should be part of any prior art examination.

**The Issue of Derivatives**

The CBD has recognized biotechnology as any technological application that uses biological systems, living organisms, or derivatives there of, to make or modify products or processes for a given specific use.<sup>15</sup> Clearly, markets and institutions worldwide consider the biotechnological use of genetic resources of actual and potential value for a number of economic sectors - particularly agriculture - and for novel bioindustrial products such as biopharmaceuticals, nutraceuticals, cosmeceuticals, dermaceuticals, and bioinformatics.

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<sup>15</sup> CBD, Article 2.

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According to the CBD definition, biological resources includes genetic resources. In addition, the Andean Community recognizes the actual and potential value of using a genetic resource or its derivatives. In this context, the Andean countries define derivatives as “a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings”.<sup>16</sup>

In fact, access to derivatives is the most frequent form of genetic resource use. The importance of their inclusion within the scope of the IR-ABS arises from the fact that countries of origin exercise sovereign rights over their derivatives. Access granted for specific uses of derivatives, therefore, does not include the property of these derivatives or their inherent biochemical information. Moreover, if derivatives are excluded from an IR-ABS, most of the potential value and benefits of adding value to derivatives will be monopolized by large corporations from developed countries.

As result of ignoring derivatives in the IR-ABS, indigenous and local communities will become the real losers, since in developing countries of origin an important part of traditional knowledge is related to derivatives.

Opportunistic users of genetic resources could ruin the construction of networks of reciprocal confidence, benefit-sharing, and thus frustrate efforts of long-term cooperation among Parties. In addition to the negative effect of ignoring derivatives, intellectual property rights inappropriately focused on private rents and the exclusion of competitors, may result in monopolies on value-added derivatives that would impede technological innovation and the transfer and dissemination of biotechnology.

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<sup>16</sup> Decision 391, Article 1.