

The Andean Community's New Industrial Property Regime: Creating Synergies between the CBD and Intellectual Property Rights

By Manuel Ruiz

What are the impacts of intellectual property rights and, particularly, of patents on inventions and plant breeders' rights, on efforts to conserve and sustainably use biological diversity?

This question has been the subject of intense debate and speculation in many national and international fora ever since the Convention on Biological Diversity (CBD) incorporated in its text explicit references to intellectual property rights (Article 16) and recognised that these could affect its effective implementation. If we add to this the rules on patenting life forms of the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs Article 27.3(b)) the controversy deepens on issues such as access to genetic resources, equitable sharing of benefits arising from the use of these resources, technology transfer, and the protection of indigenous communities' knowledge, innovations and practices.

There are, however, practically no precedents of intellectual property regimes that draw an explicit and direct link between these rights and biological diversity, integrating the concepts of 'genetic resources' 'traditional indigenous knowledge' and 'biological heritage'.

The Context of Decision 486

It is legitimate to question intellectual property systems per se, as well as their impacts on developing countries' potential scientific and technical development and, in particular, a range of ethical concerns arising from patenting life forms. The concept of 'bio-piracy' well reflects the underlying tensions in international negotiations on these issues.

Decision 486 of the Andean Community¹ on a Common Industrial Property Regime², adopted on 14 September 2000, contains a number of extremely interesting elements that allow us to envisage a future where 'megadiverse' countries that traditionally provide biological material – consequently used in inventions and protected by patents – could share the benefits arising from access to and the use of this material. It also offers a possibility for these countries to exercise greater control on the use of this material by pharmaceutical, biotechnology and agro-industrial companies.

With Decision 486, which entered into force on 1 December 2000, the Andean Community again finds itself at the forefront of progress and legislative innovation, which it already demonstrated with the adoption of Decision 391 on the Common System of Access to Genetic Resources in 1996. The new Andean Community regime on industrial property contains a series of provisions directly related to biological diversity and the protection of indigenous communities' traditional knowledge, thus establishing links between the CBD and a regional industrial property regime, which only a short time ago were considered extremely complicated and close to unviable by international negotiators and political circles.

While Decision 486 and its rules on patented inventions explicitly recognise in several instances that its implementation may generate impacts on biological diversity, it also creates certain synergies

between rules on biological diversity and traditional knowledge on the one hand, and the intellectual property rights system on the other.

Linking IPRs and Biodiversity

In a unique provision in a sub-regional industrial property legislation, Article 3 of Decision 486 (on Biological, Genetic and Traditional Knowledge Heritage) states that

The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result,

the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.³

In other words, the acquisition of rights or protection through, for instance, patents or even plant breeders' rights cannot (or must not) hurt Member Countries' or their communities' interests with regard to biological heritage or traditional knowledge.

Article 3 also provides that

Member Countries recognise the right and authority of indigenous, African American and local communities to decide on their collective knowledge.

This explicitly implies the governments' recognition of the indigenous intellectual contribution for whose protection mechanisms eventually need to be developed.

And finally, Article 3 states that

The provisions of this Decision shall be applied and interpreted in such a way that they do not contravene the stipulations of Decision 391 and its effective amendments.

This makes a direct link between the patent system and the regime of access to genetic resources, as many of these patents – particularly in the field of biotechnology – arise directly or indirectly from genetic material originating in Member Countries.

Patentable Material

While Article 14 of Decision 486 requires that patents be granted for inventions, Article 15 lists materials that will not be considered as inventions. These include in Article 15(b)

any living thing, either complete or partial, as found in nature, natural biological processes, and biological material that exists in nature or is capable of being isolated, including the genome or germplasm of any natural living thing.

Art. 15(b)'s reference to a 'natural living thing' is interesting as it indicates that in its implementation genomes or germplasm of 'non-natural' living things would be patentable, that is to say materials that may have resulted from human biotechnological interventions.

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Getting back to the link between the system of access to genetic resources and the patent regime, the Decision's Article 26 establishes that the application for a patent for an invention must contain

(h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries.

Paragraph 26(i) further specifies that the application must include *a copy of the document that certifies the license or authorisation to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested were obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations.*

This means that the applicant must secure the community's consent and present a document that proves it when attempting to patent an invention arising either directly or indirectly from traditional knowledge.

Another interesting point is that, consistent with Article 75, the competent national authority in industrial property rights could decree outright, or on request by any person at any moment, the absolute nullity of a patent in cases where

(g) the applicant failed to submit a copy of the contract for access to that genetic material when the products or processes in respect of which the patent is being filed were obtained and developed on the basis of genetic resources or their byproducts originating in one of the Member Countries; or

(h) the products or processes whose protection is being requested were obtained or developed on the basis of traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, if the applicant failed to submit a copy of the document certifying the existence of a license or authorisation for use of that knowledge originating in any one of the Member Countries.

A possibility thus exists for third parties to question the grant of a patent based on the suppositions above, and if these are confirmed, the patent can be annulled.

In conclusion, the mechanisms proposed in Decision 486 could be used to ensure that the CBD's general principles of access to genetic resources, benefit-sharing and respect for indigenous communities' knowledge, innovations and practices are effectively taken into account in the implementation of intellectual property systems. They are an important contribution to the quest for mechanisms to make intellectual property rights compatible with the Convention on Biological Diversity.

Plant Variety Protection

TRIPs Article 27.3(b) requires WTO Members to provide protection to plant varieties, either through patents or through a *sui generis* system. With the adoption of the new industrial property regime both now seem possible in Andean countries.

In October 1993, the Andean Community adopted Decision 345 on a Common Regime of Protection of Plant Variety Breeders' Rights. The legislation establishes the rules for the acquisition of

Breeders' Certificates, which protect the rights of those who develop new plant varieties that are stable, homogeneous and distinguishable.

In conformity with Article 24 of this Decision, the holder of this exclusive right can prevent third parties from undertaking without his consent a number of actions with regard to reproduction, propagation or multiplication of the protected variety, including *inter alia* its production, offer on sale, sale, exportation and importation. Decision 345 maintains an exemption for researchers (to allow continued improvement of the protected variety – Article 25). It also contains a farmer's exemption, which allows the reuse of this material in consequent harvests, although this is left to the discretion of each of the Member Countries (Article 26). Finally, the Sub-regional Committee for the Protection of Plant Varieties decided to extend protection to essentially derivative varieties. All Member Countries have already established regulations for the implementation of Decision 345.

This is an important reference that calls for a definition of double protection through Breeders' Certificates and through patented inventions, as Article 54 of Decision 486 gives the impression that patents could also apply to plant varieties. Indeed, while Decision 345 serves as an *ad hoc* (or *sui generis*) mechanism to protect new varieties, it does not exclude the possibility that they could be protected through other means. What is absolutely clear and evident is that components of varieties protected through Breeders' Certificates can be patented. This implies a complementarity and a high degree of total protection as it concerns both the variety and its specific components. It also has important consequences for the potential use of the protected variety.

Finally, it is worth thinking about the eventual impacts of this mechanism on agro-biodiversity. While it could promote monoculture and homogenisation, one can also argue that Andean zones – where this type of culture is not really viable due to agro-ecological conditions and farming practices – would not be affected from the incorporation of protected varieties in patent legislation. In fact, Andean farming based on agricultural diversification, has shown itself highly resistant to the loss of genetic variety. This has led to the preservation of an immense diversity, which in any case finds itself affected by other factors, such as the abandon of the rural environment, the influence of trade (not necessarily related to protected plant varieties) and the modernisation process. Clearly, there now is much to evaluate with regard to the direct impacts of these systems on agro-biodiversity.

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ENDNOTES

¹ The Community of Andean Nations consists of Bolivia, Colombia, Ecuador, Peru and Venezuela. It enjoys regulatory authority through Decisions and Resolutions. As a rule, Decisions need no internal approval processes and become national law automatically upon their publication in the Community's Official Journal.

² Intellectual property is divided into two categories: *industrial property*, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source; and *copyrights*, which protect literary and artistic works, as well as the rights of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

³ All quotes from Decision 486 are unofficial translations.