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INTELLECTUAL PROPERTY, TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

RECENT LEGISLATIVE DEVELOPMENTS IN THE ANDEAN COMMUNITY

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This paper has the objective of briefly outlining the most recent legislative developments in the Andean Community in relation to Traditional Knowledge (TK) and genetic resources. In particular, it addresses the main links between Directive 391[2], which entered into force on July 2, 1996, and established the "Common Regime on Access to Genetic Resources", and Directive 486, which entered into force on December 31, 2000, and revamped the "Common Industrial Property Regime". The characteristic that stands out in both bodies of law is the creation and implementation of legal mechanisms that seek the protection of TK associated to genetic resources, i.e. the intangible components found in those resources.

I. INTRODUCTION

A fundamental aspect about regulating access to genetic resources and the TK related to it is that, especially for biodiversity-rich developing countries, that biodiversity and its related knowledge amount to a comparative advantage that must be protected from unfair exploitation by developed countries. Thus, such a protection would allow developing countries to better take part in global markets and improve their economic performance.

The Andean Community comprised by Bolivia, Colombia, Ecuador, Peru and Venezuela shares and posses an enormous biological and genetic heritage. Specifically, three of these countries –Colombia, Ecuador and Peru- have been included in the list of the twelve "mega diverse countries" where between 60 to 70 percent (and maybe even more) of all the biological diversity that is known to exist in the planet can be found.[3] Moreover, in most of the Member Countries there exists considerable populations of indigenous and Afro-American communities, making the advocacy of the adequate promotion of TK a fundamental policy issue for us.

Furthermore, the fact that the geographic distribution of genetic resources and the multi-ethnicity of the Andean Community Members does not coincide with their borderlines is reflected in that two or more Member countries share basically these same biological resources and associated TK. All of this made more than imperative for Members to decide on enacting legislation that would apply on a sub-regional or communitary level. The advantages of such an approach consist on preventing an overlap and contradiction of jurisdictions that could negatively affect Members national policies both internally and externally.

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2 Directives constitute the main legislative measure within the Andean Community body of law, they are comparable to European Community Regulations, which means that they are directly applicable and have direct effect.

3 Jorge Caillaux Zazzali, Manuel Ruiz Muller, "Acceso a Recursos Genéticos: Propuestas e Instrumentos Jurídicos", Sociedad Peruana de Derecho Ambiental (SPDA), 1998, pp. 35.

II. INFLUENCES OF THE CONVENTION ON BIOLOGICAL DIVERSITY

All the Andean Community Members have signed and ratified the Convention on Biological Diversity (CBD), the first multilateral legal instrument that adopts and establishes principles directly related to the sustainable conservation of biological and genetic resources. Moreover, this same Convention also recognizes the fundamental role and the rights of the indigenous and local communities in the development and enhancement of biological and genetic resources through the TK developed by them.[4] So, because of this, the need to draft and adopt an Andean body of law that would reflect the CBD compromises assumed, and that would facilitate their effective application was addressed by way of Directives 391 and 486.

Other principles which have also permeated from the CBD to the Andean Body of law are: the assertion of the sovereign right of member countries over the use and exploitation of their genetic resources; the right to define and determine the conditions of access to these resources; and, the fair and equitable distribution of benefits product of the by-products and commercial or industrial applications of the use of those genetic resources and their intangible components[5]. Moreover, the Common Regime on Access to Genetic Resources includes numerous provisions for the protection of TK.

An essential element to both Directives, and which is one of the primal CDB principles enshrined in Andean Communitary legislation, is that of Prior Informed Consent (PIC). This means that anyone wishing to access TK associated to biological resources for scientific, commercial, or industrial application within the Andean Community is required to previously secure the PIC of the holders of that knowledge. All in all, being the State the final authority in charge of approving any genetic resource transfers. So, the potential user of any genetic resource or associated TK must also take into consideration if there are owners, holders or administrators of the Knowledge and/or property in which the genetic resources are found, i.e. the native, Afro-American and local communities who posses them.[6]

III. LINKS BETWEEN DIRECTIVES 391 AND 486

In order to protect genetic resources and the associated TK, a direct relationship between Directive 391, in force since July 1996, and Directive 486, in force since December 2000, was necessary. To be able to clearly visualize these links we will outline and compare the main elements found in both pieces of legislation.

Directive 391 main elements can be summarized as follows:

- To recognize the sovereign right of Member Countries over the use and development of their biological[7] and genetic[8] heritage.

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4 Articles 1, 8 (j) and 15 of the Convention on Biological Diversity enshrine the principles of sustainable conservation of biological resources, State sovereignty over its biological resources, access subject to mutually agreed terms and access subject to Previous Informed Consent.

5 That is the Traditional Knowledge of the indigenous, Afro-American or local communities associated to biological/genetic resources.

6 Supra 3 pp. 14. Directive 391 and Directive 486.

7 Individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products.

8 All biological material that contains genetic information of value or of real or potential use.

- To establish the conditions for a fair and equitable distribution of benefits product of the access to the genetic resources through the use of the legal fiction of the access contract[9];
- To set the foundation for the recognition and valuation of genetic resources, its by-products and, most importantly, the intangible components[10] related to them, especially those that deal with TK of the indigenous communities;
- To promote the consolidation and development of scientific, technological and technical capacities at the local, national and sub-regional level;
- To create a Competent National Authority[11] in charged of applying Directive 391 provisions of the Common Regime on Access to Genetic Resources and to ensure their performance; and,
- To strengthen the negotiating capabilities of the Member Countries in other fora.[12]

Directive 486 main elements related to the protection of TK associated with genetic resources are the following:

- It provides for the safeguarding and respect of the genetic heritage of Member countries together with the traditional knowledge of their indigenous, African American, or local communities;
- It establishes that any request for the granting of patents on inventions that have been developed from that genetic heritage or that TK shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law;
- It states the Member Countries recognition of the right and authority of indigenous, African-American, and local communities in respect of their TK;
- It states that all the provisions stipulated in Directive 486 can only be applied and interpreted in such a way as to not contravene the provisions of Directive 391;
- It requires that applications for patents, which contain or were developed from genetic resources originating in one of the Member Countries, when filed before the competent national authority, submit a copy of the access contract and, if applicable, a copy of the document that certifies the license to use the TK associated to the genetic resources used in the development of the patent; and,
- It allows for the invalidation or nullification of a patent, ex-oficio or at a third party request, if the applicant granted the patent failed to submit a copy of the access contract to the genetic material used, and, when pertinent, a copy of the document certifying the existence of an authorization for use of that associated TK, when both originated in one of the Member Countries.

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9 An agreement between the Competent National Authority in representation of the State, and a person that establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component.

10 Art. 1 of Directive 391 defines intangible components as: " all know-how, innovation or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes."

11 State entity or public institution appointed by each Member Country, authorized to supply the genetic resource or its by-products and therefore to sign or supervise the access contracts, to take the actions provided for in this common regime and to ensure their performance.

12 INDECOPI, "Propuesta de Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas y Acceso a los Recursos Genéticos", Documento de Trabajo, El Peruano, 1999.

In this vein, there exists an intimate relationship between both Directive 391 and Directive 486. This because whereas the first regulates access to genetic resources, and the latter regulates Industrial Property, and, particularly the granting of patents, the need to coordinate both bodies of law in order for Decision 391 to be effective was, as stated before, an inevitable necessity. So it was through Directive 486 that an important gap in the practical applicability of Directive 391, in aspects related to patent requests, was addressed. As can be seen, in both the Common System created with Directive 391, and the revamped Common Industrial Property Regime set out by Directive 486, a clearly established mechanism to control access to genetic resources and the use of TK associated to them was created.

This is further exemplified by the requirements set out in article 3 of Directive 486 which state the obligation of Andean Community Members to ensure that any protection given to any intellectual property elements in a patent has to be subsumed to first having safeguarded and taken into account the respect of the biological and genetic heritage, in conjunction with the TK associated to that genetic heritage which originated in the indigenous, African-American, or local communities located in their territories.

Thus, the granting of patents on inventions in the Andean Community is based on the presumption that any inventions product of the use of material obtained from the genetic heritage or its associated TK are to be subordinated firstly to the acquisition of such material in accordance with international, communitarian[13] and national law. All of which means, in the case of an Andean Community Member, that there exists the obligation for the potential user of those genetic resources and of the TK associated to them, to file a copy of the access contract before the competent national authority, which in sum means the embodying, by that Directive, of the principle of Previous Informed Consent.

III. A. PATENT APPLICATION REQUIREMENTS AND NULLIFICATION OF A PATENT

Articles 26 and 75 of the same Directive 486 clearly set out specific provisions, on the one side, about what a patent application must contain in order for it to be considered and approved, and, on the other side, on the standards for the invalidation or nullification of a granted patent.

The relevant requirements found in both articles, which work from their own legal perspective, and that are related to the protection of TK and access to genetic resources are: a) the filing of a copy of the contract for access; and, b) if applicable, a copy of the document that certifies the license or authorization, issued by the indigenous, African-American, or local communities of the Member Countries, to use their TK.

Thus, anyone, be it particular inventors or pharmaceutical transnational companies, that wish to access those resources must file an application and sign an access contract with their suppliers. It must be understood - in accordance with the principle of sovereign right of Member countries- that the final supplier[14] is the State, represented by the competent national

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[13] Andean Community Law, i.e. Directives 391 and 486.

[14] A person empowered by Directive 391 and complementary national legislation; and, if applicable, a person empowered, through an access contract and pursuant to Directive 391 and complementary national legislation

[Footnote continued on next page]

authority. Furthermore, any and all access contracts that may be negotiated must also take into account the rights and interests[15] of the original suppliers of the genetic resources –i.e. of the indigenous, African-American and local communities who posses them-, and their by-products and intangible components. Moreover, if access to a resource that includes an intangible component is requested, the fair and equitable sharing of benefits that arises from its use must also be provided for in an annex to the main contract.[16]

III. B. DIRECTIVE 391 COMPLEMENTARY PROVISIONS AND ITS LINKS TO DIRECTIVE 486

With Directive 486 the complementary provisions set out in Directive 391 were also duly addressed. This can be especially seen when comparing Directive 391 Second Complementary provision with Article 75, letters g) and h) of Directive 486. Both construe the legal fiction that no right or rights, including intellectual property rights, shall be acknowledged by any of the member states, to genetic resources, its derivatives or related intangible components obtained in violation of the Common System's terms for access to genetic resources and the Industrial Property Regime patent requirements; therefore, again, stating the need to present a copy of the access contract and a copy of the document that certifies the existence of a license or authorization to use the traditional knowledge by the holders, owners or possessors of that associated TK and genetic heritage.

The same situation occurs with Directive 486 Article 26, letters (h) and (i) constructions since they mirror the spirit and regulate the specific conditions set out in the Third Complementary Provision of Directive 391. Thus, in practice, it is now possible for the competent national authority to verify the origin of the genetic material from which a product or by-products were developed, and also determine the origin of the material used in a filed patent request. So, both Directives constitute a symbiotic mechanism, which regulate access to biological/genetic resources and allow for the protection of the associated TK or intangible components found in them.

Following the same line of thought established in the above mentioned provisions, Article 35 of Directive 391 is mirrored in article 26 (i) of Directive 486 when it provides for the requirement, by the potential user of a genetic resource, for the filing of a copy of the document that certifies PIC from the indigenous, Afro-American, or local communities in case that the potential user makes also use of the TK that belongs to those communities, and which is related to the genetic resource he wants to exploit. What we are talking about here is about those intangible elements part of the invention, which the user wants to patent as his/hers/theirs, originated in or product of the TK that belongs to those communities.[17]

[Footnote continued from previous page]

to supply the biological resource that contains the genetic resource or its by-products and/or the intangible component associated with that genetic resource or its by-products.

15 That is, over their genetic resources and/or over, if applicable, their associated TK.

16 On this point the provisions must be understood to comprise, as well, local and indigenous or Afro-American communities if they are owners, holders, or administrators of the property in which the genetic resources are found or the traditional knowledge was applied.

17 In this way, Directive 486, effectively, puts into practice the recognition of the value of the rights and decision making faculties of the indigenous, Afro-American, and local communities in relation to the access and use of their traditional knowledge associated to the genetic resources and its by-products, which were provided for by article 7 of Directive 391.

Finally, Article 75, letters g) and h) provides that as a consequence of non-compliance with the above mentioned requirements, any patent applications can be subject to refusal or rejection, and patents granted in favor of inventors who failed to submit the access contract might be invalidated or revoked, ex-oficio by the competent national authority, or at the request of a third party.

IV. CONCLUSION

Within this context, although some might conclude that by making use of the existing Intellectual Property Regime (IPR) the Andean Community members have somehow lessened their stand on the creation of a "sui generis[18]" system for protection of TK and biological resources, it must be stated that for us the use of the IPR system does not prejudge our position in this regard. What has been done is to establish requirements that only complement any "sui generis" legislation that will be created to protect TK and its associated biological resources.[19] As it was already stated in the Eight Temporary Provision of Directive 391.[20]

It should be borne in mind that Andean Member Countries, as an answer to the disparity in bargaining power of the parties usually involved in these type of contracts –i.e. the indigenous, local and Afro-American communities and the Trans National Companies-, due to the high transaction costs of negotiating such agreements, and because of the secrecy of the contracts or bilateral agreements directly negotiated between the aforementioned[21] deemed it necessary to adopt legislation that would regulate and protect that knowledge and their associated biological/genetic resources from unfair exploitation.

This makes it more than obvious for all countries as is the case of the Andean Community Member States, to adopt or to initiate the process of formulating standard form rules and norms for access contracts, so as to ensure the compliance with the principles of: State sovereignty over biological resources, Previous Informed Consent, equitable sharing of benefits, and respect of traditional values and forms of life of those communities. All of which, under the idea of reducing transaction costs, has the object of protecting the TK of the Indigenous, Afro-American and local communities, associated or not to biological resources.

It this regard, it must be stated that in the process of writing access and benefit-sharing legislation it is important that any legal measures developed should be flexible and not unduly complicated so as to keep transaction costs reasonably low, always taking into consideration, before the drafting of any legislative measure, the interests, costumes and traditional practices of those indigenous and local communities since they are the ones who will be directly

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[18] A sui generis system for protecting Traditional Knowledge associated or not to biological resources, takes into account the costumes, practices and collective rights of the indigenous, Afro-American and local communities.

[19] TD/B/COM.1/EM.13/2 United Nations Conference on Trade and Development pp 13.

[20] Directive 391, Temporary Provision, **EIGHT.-** The Board shall draw up, within a period of three months after the Member Countries present their national studies, a proposal to establish a special regime or a harmonization regulation, as applicable, aimed at reinforcing the protection of know-how, innovations and traditional practices of native, Afro-American and local communities, in keeping with the provision of Article 7 of this Decision, ILO Convention 169 and the Agreement on Biological Diversity.

[21] Obligations therein which are not binding on third parties and that could not necessarily comprehend a just and equitable sharing of benefits.

affected by such measures. It is therefore clear that the establishment and adoption of legal regimes that regulate access to resources that require of PIC and the signing of a legally binding agreement between the relevant parties constitute one of the best solutions to the question of how to protect genetic resources and the TK associated or not to them.

The need to reach agreements at the multilateral level in order to adequately protect, through an effective sui generis system, Traditional Knowledge, related or not to biological resources, and expressions of folklore is a must for the international community. Without the adoption of a comprehensive international convention in this regard, which effectively coordinates with the Convention on Biological Diversity, ILO Convention 169[22] and TRIPS, any and all national, sub-regional, and regional efforts taken to protect such knowledge, in ways that benefits all parties involved, would be totally and absolutely undermined. This is the challenge we now face, it is up to us and our governments to meet it.

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[22] International Labor Organization Convention on Indigenous Peoples Rights and Duties.