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Traditional Knowledge and Access to Genetic Resources
Critical Elements towards a National Policy and Legislation for Chile

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Abstract

Traditional knowledge, hereinafter TK, is a broad concept that is deeply rooted in the life of billions of people, especially within the indigenous communities that have developed it either in the North or in the South. TK has multiple manifestations in several fields, from medicinal uses of plants and herbs, to artistic creations. Bio-prospective activities during the 90 have brought the TK problematic to the international fora: the indigenous communities, South Governments, NGO's and some other groups have complained against the everlasting misappropriation of TK. Since genetic resources are scarce in the North, TK has been reaching increasing value for transnational companies and Universities research groups who have turned their interest to it as a critical source of their R+D projects to advance their business and academic agendas. This work addresses the problematic of TK as well as the Access to Genetic Resources and the benefit Sharing derived from it (hereinafter ABS). It intends to contribute to clarify some still obscure issues for Chile and to show some valuable international experiences to advance in the process of drafting a national strategy, policy and legislation to regulate the issues surrounding TK and AGR. The work calls for a collaborative approach between the main stakeholders to better achieve huge humanity challenges as fighting hunger and catastrophic diseases. The first part addresses the main concerns about TK from an international legal perspective, explaining different views and issues, some of them quite controversial. The second part brings up an interesting new approach to align conflicting interest in the international world, the so-called public-private partnership. The third part is an attempt to provide guidance to decision makers in Chile and eventually some other developing countries on how to face such a process having in mind the fulfillment of the principles and objectives surrounding TK and ABS. The work ends with some conclusions and thoughts regarding the matter.

Introduction

Traditional knowledge, hereinafter TK, is a broad concept that is deeply rooted in the life of billions of people[1], especially within the indigenous communities that have developed it either in the North or in the South. TK has multiple manifestations in several fields, from medicinal uses of plants and herbs, to artistic creations. Bio-prospective activities during the 90 have brought the TK problematic to the international fora: the indigenous communities, South Governments, NGO's and some other groups have complained against the everlasting misappropriation of TK. Since genetic resources are scarce in the North, TK has been reaching increasing value for transnational companies and Universities research groups who have turned their interest to it as a critical source of their R+D projects to advance their business and academic agendas.[2] Knowledge is playing an increasingly important role in the global economy, although there is a huge asymmetry in the world economy: nearly

[1] It has been said that TK provides a daily means to face health problems for nearly 80% of the people in developing countries. See Brandon Tobin, Towards an International Regime for Protection of Traditional Knowledge: Reflections on the role of Intellectual Property Rights, 2004

[2] Annual estimations of global markets of products stemming from genetic resources are in between 500-800 billion dollars (in the following sectors: pharmaceutical, botanic medicine, main agriculture cultivars, horticulture, vegetal protection, cosmetic, personal care). "The Commercial Use of Biodiversity", Kerry Ten Kate and Sarah A. Laird, Earthscan, London, 1999.

93% of patent applications in the world originate in North America, Western Europe and Japan[3].

As we will see in a more detailed way later on, the international community has set forth just some general orientations to address the matter, basically trough the Convention on Biological Diversity (hereinafter CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter ITPGRFA), leaving ample room to each country to develop specific national strategies, policies and legislations. (Unfortunately we will not be able to review how TK has been addressed in the United Nations Declaration on the Rights of Indigenous Peoples approved by the General Assembly at the very days in which this work reached the print process, during September 2007, after 20 years of negotiation, although its Art. 31 expressly sets foth that "indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.")

The protection of TK have been addressed from different point of views and goals: some have highlighted a "defensive" approach, having in mind the avoidance of misappropriation and "bio-piracy" as the main objective; while some others have pointed out a "proactive" approach, in which TK's sustainable use as well as benefit sharing with the local and indigenous communities that have produced it are the fundamental criteria for protecting.

Latin America is an essential part of this process because in some of its countries lay an important bunch of these genetic resources and ancestral TK practices. Eight Latin-American countries are part of the eighteen members group of Like-Minded Bio-diverse countries launched in 2002, which possess more than the 70% of the total of genetic resources of the world.[4]

Regarding Chile, even though it is not part of the aforementioned group, it does have an important bunch of endemic genetic resources. The country's strategy of development is based on an open economy that fosters interchanges and partnerships with international actors as a way to reach more innovation[5], what is a central element on such strategy. Chile also has pending critical processes with its indigenous people. Setting policies and municipal legislation to address TK and access to genetic resources is imperative to advance in enhancing living conditions for indigenous communities (of course along with several other issues to be considered in that process) as well as strengthening the activities that nurture such innovation process.

The visions of the interested parties all over the world are fairly opposed and even passionate. Creative ways to address the subject matter are increasingly necessary to foster a view that, at one hand, permits to generate the proper means to have the indigenous communities involved in the process, and sharing the benefits of commercially exploiting TK, if they eventually decided to do so; and at the other, allows national and international partnerships with R+D groups and companies that are able to promote and increase TK's use and value for important goals as struggle against hunger and catastrophic diseases all over the world, but especially in developing and least developed countries. This paper intends to contribute to clarify some still obscure issues for Chile and to show some valuable international experiences to advance in such a process. The first part addresses the main concerns about TK from a legal perspective, explaining different views and issues, some of them quite controversial. The second part brings up an interesting new approach to align conflicting interest in the international world, the so-called public-private partnership. The third part is an attempt to provide guidance to decision makers in Chile and eventually some other developing countries on how to draft national policies and legislation that promote the fulfillment of the principles and objectives surrounding Genetic Resources Access and TK, to end the work with some conclusions and thoughts regarding the matter.

I The international legal system and the problematic of Traditional Knowledge and the Access to Genetic Resources

There are two important points of view through which TK has been addressed by International Law doctrines:

1.1. The (legitimate) Access to Genetic Resources v/s Misappropriation and Bio-piracy

1.2 The Intellectual Property Rights (IPR's) v/s the Public Domain

We will review some of the most relevant issues in each of these two ambits.

1.1 The (legitimate) Access to Genetic Resources v/s Misappropriation and Bio-piracy

Since access to genetic resources has become a fundamental but scarce piece -at least in the developed world- to carry out R+D projects that intend to struggle against hunger and widespread lethal diseases, specially at the least developed and developing countries level -paradoxically plentiful of

[3] See Patent Report 2006 Statistics on Worldwide Patent Activity, WIPO

[4] See press release at http://www.biosafety-info.net/bioart.php?bid=245, last visited on August 5, 2007.

[5] See Consejo de la Innovacion Chile, Towards a National Strategy of Innovation for Competitiveness, 2006.

such resources-, the international community has seen merit to agree in some principles and modalities to address it. An important bunch of these genetic resources have been possessed since long ago by indigenous communities and represent one of the most important parts of TK.
There are two international treaties that expressly address this issue:

1.1.1 The Convention of Biological Diversity (CBD)
This binding agreement was approved in 1992 and has been signed by 188 countries so far, although the US has not adhered yet. CBD is an authentic "global treaty", with high participation and acceptation at the international level, and a pioneer in its objectives and its ambit of application.[6]
Art. 1 sets forth the main principles as follows:
Objectives: "The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding".[7]
It also sets forth in its Art. 15.2:
"Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."[8]
Art. 15 also establishes:
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.[9]

Therefore, it can be said that the CBD's international system clearly sets forth as main elements as follows: the **right to access** for the signing parties it depends on the conditions set forth by the **sovereignty of national legislations** and the competent authorities of each country, subject to the **prior informed consent** (PIC) of this, and always having the parties reached a **mutual agreement** that ensures the **fair and equitable sharing of the benefits** arising out of the utilization of genetic resources.

1.1.2 The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
According to FAO, "plant genetic resources for food and agriculture are crucial in feeding the world's population. They are the raw material that farmers and plant breeders use to improve the quality and productivity of our crops. The future of agriculture depends on international cooperation and on the open exchange of the crops and their genes that farmers all over the world have developed and exchanged over 10,000 years. No country is sufficient in itself. All depend on crops and the genetic diversity within these crops from other countries and regions". [10]
This treaty took seven years of negotiation. Through FAO's Resolution 3/2001, the International Treaty on Plant Genetic Resources for Food and Agriculture was adopted, in November 2001. It is in harmony with the Convention on Biological Diversity adopted in 1992. Its predecessor was the former FAO Undertaking on Plant Genetic Resources agreed in 1983. This Treaty covers all plant genetic resources relevant for food and agriculture.
The Treaty defines plant genetic resources as "any genetic material of plant origin of actual or potential value for food and agriculture". FAO points out that "through the Treaty, countries agree to establish an efficient, effective and transparent Multilateral System to facilitate access to plant genetic resources for food and agriculture, and to share the benefits in a fair and equitable way. The Multilateral System applies to over 64 major crops and forages. The Governing Body of the Treaty, which will be composed of the countries that have ratified it, will set out the conditions for access and benefit sharing in a "Material Transfer Agreement"".[11]
The Multilateral System provides the resources for utilization and conservation in research, breeding and training. The Treaty provides for payment of an equitable share of the resulting monetary benefits, if others may not use this product without restriction for further research and breeding. If others may use it, payment is voluntary.[12]

Some of the crucial elements addressed by the Treaty **are the sharing of the benefits of using plant genetic resources** for food and agriculture through information-exchange**, access to and the transfer of technology, and capacity building**. A funding strategy to mobilize funds for activities, plans and programs to help, above all, small farmers in developing

[6] Carolina Lasen Diaz, The International legislative framework on Access to Genetic Resources, Equitative Benefit Sharig and the associated Traditional Knowledge Protection: IPR's relationship. 2004. Foundation for International Environmental Law and Development

[7] Convention on Biological Diversity, Article 1. At http://www.cbd.int/convention/convention.shtml last visited on 7/23/07.

[8] Id supra 7.

[9] Id. Supra 7.

[10] http://www.fao.org/ag/cgrfa/itpgr.htm, last visited July 19, 2007

[11] Id. Supra 10

[12] ITPGRFA, Article 12

countries is also foreseen. This funding strategy also includes the share of the monetary benefits paid under the Multilateral System. According to FAO, "the Treaty recognizes the enormous contribution that farmers and their communities have made and continue to make to the conservation and development of plant genetic resources. This is the basis for Farmers' Rights, **which include the protection of traditional knowledge**, and the right to participate equitably in benefit sharing and in national decision-making about plant genetic resources. It gives governments the responsibility for implementing these rights". [13]

Art. 9 sets forth: "**Article 9 – Farmers' Rights**

9.1 The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centers of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

9.2 The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

(a) Protection of traditional knowledge relevant to plant genetic resources for food and agriculture;

(b) The right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and

(c) The right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate."[14]

With regard to IPR's, the Treaty expressly states: "Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System"[15]

Misappropriation and Bio-piracy will be reviewed along with the matters addressed in the following section.

[13] Id. Supra 10

[14] ITPGRFA Article 9

[15] ITPGRFA Article 12.3 d)

1.2 The Intellectual Property Rights (IPR's) v/s the Public Domain

Since some of the misappropriation cases of TK have resulted in the granting of patents in the US and Europe, and some others have been related to images susceptible to be protected under copyrights, several of these issues have been addressed under the prism of the IPR's.

legal devices adequate means to keep them protected. While not taking into account the moral rights they have, it has also been contended that the IPR's system has been built without regard to properly encompass rights that belong to a whole community, and need to be protected for longer terms than IPR's allow. It is also argued that TK needs to be broadly disseminated in order to continue to serve as a mean to struggle against hunger and lethal diseases, and IPR's are opposed to that goal because they end up restricting such a broad transmission and pass on through generation to generation. The public domain would be the right scenario to address TK problematic in this context, which is basically the protection of the indigenous communities from misappropriation and bio-piracy.

Moreover, one of the most significant ways in which the developing countries are facing the misappropriation problematic (the so called defensive protection of TK or the misappropriation option) is by publishing TK in databases that can be reachable by developed world Patent Offices, so the material within it can account as prior art (it should be noted that while doing so, the priority to file patents would also preclude for the own TK holders over the innovative products or processes that they have in custody, because of lack of novelty).[16] Some developing countries as India have claimed, in the post TRIP's negotiations, and based on the Doha Ministerial Round Declaration (which highlighted the need for further work in the TRIPS Council on protecting traditional knowledge)[17] that TRIP's be modified by including dispositions so that applicants for IP rights which consist of, or are developed from, genetic resources should identify the source of these resources and provide proof that they were acquired with the prior informed consent of the country from which they were taken. It has been stressed that such a requirement in all patent laws for the patent applicant to disclose the source of origin of the genetic resources and evidence of prior informed consent would

[16] Cfr. Carlos M. Correa, Traditional Knowledge and Intellectual Property. Issues and options surrounding the protection of TK, discussion paper, Rockefeller Foundation, 2001, hereinafter Correa, 2001 and B. Tobin (2004), supra 1.

[17] Paragraph 19 of Doha WTO Ministerial Declaration (WTO Document No. WT/MIN(01)/DEC/1) adopted on 14 November 2001, calls for the TRIPS Council to examine the issue of protection of traditional knowledge and folklore. Source: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.doc, last visited August 3, 2007.

increase transparency. It would also allow, simply by providing information, to help with the enforcement of any access and benefit sharing agreements to be properly complied.

To illustrate the point, in many traditional societies, there is a shared view that knowledge should be free for all, which contrasts with the idea of commercialization as well as monopoly rights over such knowledge when patented. Also, many traditional medicine systems are based on integrated holistic treatment that gets lost when a single molecule is isolated for commercialization. However, through commercialization of traditional medicine its health benefits can be available to a larger section of society, what entails the need of investments of large amounts of funding in research and development. If assurance of recouping those investments as well as obtaining legitimate profits cannot be given to the investors, as in the IPR's system basis, they will divert their resources. According to the IPRs Commission, "IPR's clearly may have a role in exploiting products based on traditional medicine. But the primary objective must be to promote the application of this knowledge to improve human health, rather than to generate income".[18]

Numerous authors have addressed the very concept of TK, because it entails its own scope of protection. In a recent work, Madhavi Sunder has seen it as something that is susceptible to be hold by TK holders as well as a source of new knowledge generated by them (thus deserving to be protectable for both features), in a dynamic process, asserting that "in the Knowledge Age, wealth lies not simply in access to other people's knowledge (although this is certainly important), but also in the ability to produce new knowledge and to benefit from this creation, culturally and economically".[19]Anyway, it is possible to look at the IPR's system to at least have an idea of how this property system would address the claims of avoiding misappropriation and the holders have raised benefits sharing that legitimately. Both, the UK Commission of IPR's Final Report and the Traditional Knowledge Digital Library, along with some academic papers, have provided information regarding the cases that follow (although all the claims have to do with eventual violations to IPR principles and legislation in force, there also are some claims that fit better with benefit sharing grounds, so we will group them accordingly):

[18] Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights (2002), available at http://www.iprcommission.org/graphic/documents/final_report.htm, last visited August 2, 2007, hereinafter, IPR's Commission Final Report.

[19] Madhavi Sunder, The Invention of Traditional Knowledge, 2006.

1.2.1 Claims regarding unfulfilled requirements of patentability.

These cases refer mainly to patents that have been issued regardless absence of novelty and non-obviousness.

Turmeric (*Curcuma longa*).

It is a plant that belongs to the ginger family yielding saffron-colored rhizomes used as a spice for flavoring Indian cooking. Properties that make it an effective ingredient in medicines, cosmetics and as a color dye have been also found. It can be used to heal wounds and rashes. In 1995, two Indian nationals at the University of Mississippi Medical Centre were granted US patent no. 5,401,504 on "use of turmeric in wound healing".

The Indian Council of Scientific and Industrial Research (CSIR) requested the US Patent and Trademark Office (USPTO) to re-examine the patent. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not novel. Their claim was supported by documentary evidence of traditional knowledge, including an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association.

Despite arguments by the patentees, the USPTO upheld the CSIR objections and revoked the patent. This has been a landmark case. It was the first time that a patent based on the traditional knowledge of a developing country had been successfully challenged. The legal costs incurred by India in this case have been calculated by the Indian Government to be about at US $10,000[20]

Neem

Azadirachta indica is a tree from India and other parts of South and Southeast Asia. It has properties as a natural medicine, pesticide and fertilizer. Extracts of neem can be used against hundreds of pests and fungal diseases that attack food crops. Moreover, there is evidence that the oil extracted from its seeds is used to treat colds and influenza; and mixed in soap, it is able to provide relief from malaria, skin diseases and even meningitis, at low cost.

In 1994 the EPO granted European Patent No. 0436257 to the US Corporation W.R. Grace and USDA for a "method for controlling fungi on plants by the aid of hydrophobic extracted neem oil". In 1995 a group of international NGOs and representatives of Indian farmers filed a legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of neem seeds had been known and used for centuries in Indian agricultural to protect crops, and thus was the invention claimed in EP257 was not novel.

[20] Traditional Knowledge Digital Library, http://203.200.90.6/tkdl/LangDefault/common/Biopiracy.asp#Features, last visited July 17, 2007

In 1999 the EPO determined that according to the evidence "all features of the present claim have been disclosed to the public prior to the patent application… and [the patent] was considered not to involve an inventive step". The patent was revoked by the EPO in 2000.[21]

Ayahuasca

Shamans of indigenous tribes throughout the Amazon Basin have since long ago processed the bark of *Banisteriopsis caapi* to produce a ceremonial drink known as "ayahuasca" (that means "vine of the soul". The shamans use ayahuasca in religious and healing ceremonies to diagnose and treat illnesses, meet with spirits, and divine the future. Loren Miller, an American citizen, obtained the US Plant Patent 5,751 in June 1986. Rights over an alleged variety of *B. caapi* he had called "Da Vine" were granted. According the description, it was stated that the plant was discovered growing in a domestic garden in the Amazon rain forest of South America. The patentee claimed that Da Vine represented a new and distinct variety of *B. caapi*, primarily because of the flower color.

The Center for International Environmental Law (CIEL), acting on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) – an umbrella organization representing over 400 indigenous groups – that had learned of the patent in 1994, filed a re-examination request on the patent. CIEL claimed that that a review of the prior art revealed that Da Vine was neither new nor distinct. They argued also that the granting of the patent would be contrary to the public and morality aspects of the Patent Act because of the sacred nature of *Banisteriopsis caapi* throughout the Amazon region. CIEL presented extensive and new prior art. In November 1999, the USPTO rejected the patent claim agreeing that Da Vine was not distinguishable from the prior art presented by CIEL and therefore the patent should never have been issued. However, the USPTO reversed its decision and announce in early 2001 that the patent should stand, as result of further defense from patentee.[22]

1.2.2 Claims regarding absence of benefit sharing agreements

The following cases were never taken to the courts on grounds of unfulfilled patentability requirements, although that is the main objection: stolen TK through bio-piracy practices. However, negotiations turned out in benefit sharing agreements.

Hoodia Cactus

The San have traditionally eaten the Hoodia cactus to stave off hunger and thirst on long hunting trips. In 1937, a Dutch anthropologist studying the San, who live around the Kalahari Desert in southern Africa, noted this use of Hoodia. Scientists at the South African Council for Scientific and Industrial Research (CSIR) only recently found his report and began studying the plant, resulting in a 1995 CSIR patent over the Hoodia's appetite-suppressing element (P57). Then, in 1997, they licensed P57 out to the UK biotech company, Phytopharm. Pfizer acquired in 1998 from Phytopharm the rights to develop and market P57 as a potential slimming drug and cure for obesity (a market worth more than £6 billion), for up to $32 million in royalty and milestone payments.

The San People, on grounds of misappropriation and "biopiracy" of its TK, threatened legal action against the CSI. The San claimed that CSIR had not complied the rules of the Convention on Biodiversity, regarding the prior informed consent of all stakeholders, including the original discoverers and users. An understanding was reached between the CSIR and the San, in 2002, whereby the San, recognized as the custodians of traditional knowledge associated with the Hoodia plant, will receive a share of any future royalties. [23]

Arogyapaacha

The Kani, in South India, uses this plant for medical treatment. Based on this plant, an anti-stress and anti-fatigue sports drug named Jeevani was developed. Scientists at the Tropical Botanic Garden and Research Institute in India isolated the active compounds in arogyapaacha plant, and then, based on Kani know-how, and the technology licensed to Arya Vaidya Pharmacy, Ltd. -an Indian pharmaceutical manufacturer- patents were filed. Arewa points out "a benefit sharing arrangement was established to share any benefits with the Kani from commercialization of Kani traditional knowledge".[24]

These last two cases seem to be in the right way for developing countries and would demonstrate that with goodwill on all sides, mutually acceptable arrangements for access based on prior informed consent, and benefit sharing are viable. For defenders of intellectual property as a way to approach to the TK problematic, these cases have shed light on how to secure future benefits. Even the San and the Kani have recognized it.

[21] IPR's Commission Final Report

[22] IPR's Commission Final Report

[23] IPR's Commission Final Report

[24] Arewa, Olufunmilayo, TRIPS and Traditional Knowledge, Case research Paper Series in Legal Studies, March 2006

II A new approach to align conflicting interests in the international world: Public-Private Partnerships.

In the health sector, Andrew Whang[25] has brought to our attention and interesting development within the past decade is the establishment of a number of public-private partnerships that intend to address specific diseases. Among other examples, the Global Alliance for TB Drug Development, the International AIDS Vaccine Initiative, and the Medicines for Malaria Venture represent good examples in which the public interest is fulfilled through private initiatives with mixed support and funding. They use contracts and other means to supplement or bypass the traditional incentives of the patent system while not addressing problems in the patent system as a whole.

New pharmaceutical products that will be widely accessible to the developing world use to be the focus of several of these partnerships. The means by which they do so are called "pull" mechanisms. These reward the company that is successful in the drug development process in some respect. Examples include advance purchase commitments to buy a certain amount of a drug if one is developed, or prizes for the first company to develop achieve some goal in the drug development process (e.g. phase I clinical trials).[26] Interestingly, the partnerships also may directly fund R&D for some projects as well.[27]

The process works as follow: the partnerships identify the most pressing gaps in drug and vaccine development and set priorities for each of them. They issue a competitive call for project proposals from private drug companies. The partnerships select the most promising ones for funding and/or prize commitments or advance purchase commitments.

Regarding to the patents that arise from such research, contracts are negotiated between the partnership and the particular companies it works with. Such contracts may grant the partnership exclusive rights, establish pricing agreements, or set an upper limit on the amount of profit that a company may charge for an end product.[28]

The public-private partnerships are also playing another fundamental role in supplying the developing world with very low cost or free drug treatments. Since they purchase in huge amounts, the partnerships can negotiate discounts from drug manufacturers, whether generic or brand name. Governments of local countries then apply for grants from the partnerships to fund existing health care structures able to distribute the drugs appropriately[29]. In the case of TB, drug treatments are often distributed free of charge, but under the requirement that they be ingested in the presence of a trained observer.[30] This addresses the whole process of the access problem, at least for TB.

Whang points out that "it may be most fitting for public or quasi-public entities to generate incentives and ensure access to new drugs. The social value of treating one person may far outweigh the economic costs of that treatment, because not treating that person and allowing the disease to spread imposes costs on an entire community"[31].

Regarding funding of these partnerships, it comes from governments, non-governmental organizations, and philanthropic donations. An important question with respect to public-private partnerships is whether they will be adequately funded to fulfill their missions. Also recently, a couple of interesting international institutions have emerged in fields in which R+D international and national public funding has played an important role.

In the health sector, the *Centre for Management of Intellectual Property in Health Research* and Development, *MHIR*, was created "to contribute to a world in which the ethical stewardship and creative management of intellectual property leads to better health for the poorest."[32] MIHR "also works to ensure that holders and managers of technology worldwide are aware of the need for and potential value of their technology holdings to the improvement of health in developing countries. MIHR helps facilitate transfer of those technologies to relevant institutions through building a common understanding of different stakeholders' needs, interests, capabilities and shortfalls. In this way, MIHR contributes to improvement in health by facilitating local development of appropriate, affordable innovative biomedical technologies for poor populations. Moreover, MIHR encourages technological outcomes in the form of products and new knowledge that are socially beneficial -

[25] Andrew Whang, Diseases, Drug Prices, and Developing Countries, paper presented at Prof. Robert Merges Intellectual Property Seminar, UC Davis School of Law, 2004.

[26] "Push" mechanisms are commonly operated by governments, and include tax breaks for R&D and direct funding of R&D. One example is in the U.S., where the National Institutes of Health currently spends $27 billion per year on research, much of which goes toward drug development and includes funding for clinical trials of drug candidates. Tim Hubbard and James Love, A New Trade Framework for Global Healthcare R&D, 2 PLoS BIOLOGY, 0147, 0148 (2004).

[27] Whang, Ibidem

[28] Craig Wheeler & Seth Berkley, Initial Lessons from Public-Private Partnerships in Drug and Vaccine Development, 79 BULLETIN OF THE WORLD HEALTH ORGANIZATION, 728, 731 (2001).

[29] Whang, Ibidem

[30] World Health Organization, TB ADVOCACY REPORT 2003, TUBERCULOSIS 16 (2003). Directly Observed Treatment, or DOTS, has had widespread success, though diagnosing TB is still difficult. *Id*.

[31] Whang, Ibidem

[32] MIHR's website http://www.mihr.org/index.php/?q=node/view/1, last visited July 31, 2007.

emphasis is placed on the social and economic value in pursuing a dual bottom-line of economic and social gain."[33]
In the agricultural sector, the *Public Intellectual Property Resource for Agriculture, PIPRA*, is becoming a very active and leading institution that "supports agricultural innovation for both humanitarian and small-scale commercial purposes. We bring together intellectual property from over 40 universities, public agencies, and non-profit institutes and help make their technologies available to innovators around the world".[34] According to PIPRA's website, it "serves a number of purposes, the most important of which is helping to improve agriculture in emerging economies by decreasing intellectual property barriers and increasing technology transfer. We also work with farmers and scientists in mature economies who are growing specialty crops. Finally, PIPRA helps our member institutions achieve their humanitarian mandates by making sure their technological innovations get to those who need it most".[35]
All the aforementioned initiatives are becoming important interfaces to make collaborative visions and efforts worth to contribute to align legitimate public and private interests and entities in the world to better struggle against hunger and lethal diseases. Understanding that facing such problematic has to be a join endeavor is an important lesson to be drawn from such initiatives that should be able to show a path for developing countries to better achieve long term objectives of preserving, protecting and ensuring proper ways to benefit from the genetic resources and the associated traditional knowledge, whit similar goals.

III Access to Genetic Resources and Traditional Knowledge in Chile.

3.1 Rationale for protection

Chile has plenty of genetic resources and several of these are endemic, which means they can only be found within Chile's territory. There have been bio-prospecting missions working in Chile for a long time, although there are no systematic registers of such activities (it is not legally mandatory). Patents abroad have been filed over innovations that have used a bunch of genetic resources that could have been extracted from Chile. Assurance of the use of some of our endemic biological material does exist in the case of the vinchuca (tripanosoma cruzi), and the rapamycina (whose biological material was allegedly taken from Chilean territory at Easter Island).[36]

During last June 2007, CORFO, the Chilean Development Agency, released a report with the innovation projects they have funded during the last 6 years and several of them are based in the analysis of our genetic resources, which means that Chilean Government as well as private companies and institutions are allocating substantial amount of financial and human resources on this.[37]
Chile's richness in genetic resources should be sustainable exploited, in the context of the fulfillment of all the conditions already set forth for the international regime, no matter how broad and programmatic they are so far. Reasonable paths to reconcile the interest of the country to advance in the innovation process along with the protection of our cultural heritage need to be found. The old saying "the farmer's dog" (who does not allow anyone to eat vegetables while guarding although it does not eat either), referring to the attitude in virtue of which neither Chile and its people nor alien institutions can be benefited from genetic resources and its associated TK exploitation, should be kept away from a modern policy that better allows all the interested parties to reach their goals, even if they could appear conflicting at the beginning.
Chile has concurred to sign both CBD and ITGRPFA. Although the last one has only been signed and its parliamentary ratification is still pending to become binding national legislation, the CBD already is so. However, a national strategy, policy and legislation on the subject matter have not been fully developed yet. In regard to genetic resources and TK associated with it, topics as ownership (one of the most problematic because of the Constitution requirements of legislative quorums to eventually modify it), right to access and benefit sharing arrangements with indigenous communities holders of TK under prior informed consent need to be carefully addressed in order to generate a national legal framework that is consistent with our international obligations. Probably the embryonic nature of the projects developed so far and the funding provided by Chilean Government have resulted enough guarantees for private companies to invest. However, as long as these projects become more complex and foreign investment is necessary, there will be increasing demands to have these issues solved and to provide certainty to every potential investor that endeavors can be developed in a legal context that allows and encourages R+D spending under the conditions usually agreed for this, within which, basis to recoup the amount invested and legitimately profit from it are central. We will briefly review the Chilean process on that.

[33] Ib. at supra 32

[34] PIPRA's website http://www.pipra.org/, last visited July 31, 2007

[35] Ib. at supra 34

[36] Maria Isabel Manzur, 'Experiences in Chile regarding access to genetic resources, protection of traditional knowledge and intellectual property rights', 2004. Foundation for International Environmental Law and Development.

[37] CORFO, the Chilean Development Agency, 70 cases of innovation supported by Innova Chile, 2000-2006. July 2007.

3.2 Attempts in Chile to have a national policy and binding legislation to regulate traditional knowledge in the context of access to genetic resources and benefit sharing.

Although Chile is a CBD contracting signing party since its passing in 1992, and having it properly ratified and promulgated, this is a non self executing agreement. Then, municipal legislation shall have to be passed to harmonize the current legislation related with CBD's contents in a proper way. Chile has also signed all the aforementioned international agreements regarding to access to genetic resources.

However, the concept of access to genetic resources, benefit-sharing, farmers' rights and traditional knowledge provisions in the sense that they are addressed at CBD and ITPGRFA are rather rare and almost inexistent in current Chilean legislation.

During the early 90, within the efforts of the democratic governments that followed Pinochet's dictatorship in the environmental context, a new institutionality was created, led by CONAMA, the National Commission on Environment. As part of the definition of a National Biodiversity Strategy, diverse efforts and several steps were taken inside the executive power in order to advance in the access to genetic resources field. They seemed to have been triggered by some relevant bio-prospecting activities carried out in the country at that time. The main Ministries and Agencies in charge of environmental, agricultural and livestock care were part of the study groups, (e.g. Ministry of Agriculture, of Public Goods, SAG, and INIA among the main public services). [38]

However, the political class did not fully understand what was at stake and all the efforts to persuade the National Congress to pass the necessary legislation as well as the study groups and Commissions created by the government to address this matter have almost completely vanished. Political leaders did not regard the matter as a priority.[39]

Paradoxically, a country that is allegedly leading the way for developing countries to enter to this current century in the context of the globalization process is completely lacking of policies and regulations in a fundamental matter for the development of the nation and its indigenous communities.

As a result of an agreement with the Ministry of Agriculture, INIA, the National Institute for Agrarian Innovation, is the entity in charge of the custody of the genetic patrimony in Chile. Although INIA is a serious institution, and is doing its best, without a national legal framework that validates the commitments that Chile has undertaken in the international world, all these dispositions will render just programmatic and unenforceable. Candidly, INIA's website points out: "Legal situation in Chile about Genetic Resources Access: Chile is lacking from a policy that regulates access to genetic resources, so the activity is carried out within de limits of the decision made by scientific and technical staff at the Research Institutes and Universities. There are no policies to regulate the recollections carried out by alien missions, which has generated a runaway of genetic material that represents a potential economic benefit for the country"[40]. Further, it expressly recognizes that "INIA has the authority to engage in contracts with whom require to access to these resources, with the aim of protecting the genetic patrimony of the country and to safeguard Chile's interest. However, without the existence of the national legal framework, the INIA genetic resources access system just exhorts to the good faith of the collectors".[41] This lack of a national framework as well a clearly defined public institution in charge of the process has been claimed as a real problem in the fulfillment of the objectives of protection of TK and GRA. [42]. To make things worse, although functionally INIA is an institution under the supervision of the Ministry of Agriculture, it was created as a private institution, what question its ability to develop a national normative and to enforce it.

One of the most comprehensive study undertaken on the subject matter of the regulations of access to the genetic resources, benefit sharing and traditional knowledge in Chile was carried out in 2003, and basically concludes that Chilean legislation does not even recognizes this terminology, which rather belongs to the last part of the last century[43]. The Political Constitution of the Republic addresses some environmental concerns in a very broad way. The Plant Varieties Protection Law neither refers to any of those concepts nor to the farmers' rights one. Neither does it the Patent Chilean Law. Then, it is not surprising that several of the categories involved in the subject are to be regulated just by property dispositions of the Chilean Civil Code, which dates from 1857.[44]

Chile must take proper care of all of this by passing legislation that harmonizes our current legal scenario to the international agreements that has been signing and ratifying. Acting in the international world requires seriousness from

[38] Flores and Herve. See S. Carrizosa, S.B. Brush, B.D. Wright, and P.E. McGuire. 2004. Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity. IUCN, Gland, Switzerland and Cambridge, UK, hereinfater Carrizosa, 2004.

[39] Ibid. supra 38, Carrizosa, 2004

[40] http://www.inia.cl/recursosgeneticos/politicas/situacion.htm, last visited July 18, 2007

[41] Ibid. Supra 40

[42] See Brendan Tobin, Krystyna Swiderska, Searching a common language: Indigenous participation in the development of a sui generis regime of TK protection in Peru, 2002. See also Carrizosa, 2004 at chapter 3.

[43] Ibid. Carrizosa, 2004.

[44] Ibid. Carrizosa, 2004.

our political class. Perhaps the most convincing argument for them is the increasing landscape of obligations imposed by developed world to continue to trade with developing nations: the green and labors barriers as well as the respect fort minorities will probably determine in the future which country will be favored, at least in commerce with Europe, so it is much better to start developing the national legal frameworks that insert Chile in the international system as a country that is reliable, progressive and complies with international standards.

3.3 TK concerns to be taken care of in the design and drafting of a national policy and legislation

So far, there is plenty of international bibliography regarding several concerns surrounding TK. The main one seems to be the misappropriation of TK and genetic resources. However, this is just one of the issues that need to be raised and addressed.

Perhaps the International Commission on IPR set up by the UK Government is the international entity that has better understood what the developing countries need to address to fully and properly regulating the subject matter in their national policies and legislations.

The Final Report of the Commission states the following concerns:

- "Concern about the loss of traditional life styles and of traditional knowledge, and the reluctance of the younger members of the communities to carry forward traditional practices"[45]. There is broad consensus about this point, which can entail critical losses for TK. If the current young generations do not continue to practice the ancestral knowledge, they will not be able to either keep it or pass it on the new ones. This of course is a matter that goes far beyond the TK itself, and has to be with how our states assume that local and indigenous communities cultural heritage needs to be taken care of and protected, and its further use promoted.
- "Concern about the lack of respect for traditional knowledge and holders of traditional knowledge"[46]. Biases have emerged about this by not regarding TK as "official" science. By not giving TK the credit that in fact deserves, and generating incredulity about it, TK holders lack from the necessary societal acknowledgement they should have to continue to develop the work they have done so far.
- "Concern about the misappropriation of traditional knowledge including use of traditional knowledge without any benefit sharing, or use in a derogatory manner".[47] This is one of the several ways in which TK and its holders are disrespected by our societies and is addressed throughout this article[48].
- "Lack of recognition of the need to preserve and promote the further use of traditional knowledge" [49] While making the emphasis just in the economic value of TK, intrinsic cultural, social and even religious value is set aside. It is not just about to protect TK holders from misappropriation, but how to promote TK itself to, consequentially, how to make sure that it continues to pass on to new generations.

3.4 Drafting Policies and legislation about Genetics Resources ABS and TK in Chile and eventually some other developing and least developed countries in the South.

In order to make a contribution on how to develop suitable policies and legislation that cover TK problematic in the most adequate way, we will review some key principles, policy objectives and legal tools that may be useful to handle the process in the South. They stem from the international and national legal frameworks, from the work of international organisms, as well as from the most relevant legal doctrines developed so far.

[45] IPR's Commision Final Report

[46] Ibidem

[47] Ibidem

[48] See supra 1.1, infra III

[49] IPR's Commission Final Report

3.4.1 Principles and objectives for consideration of policy makers

Equity

This principle is probably the cornerstone of the system. In the new international architecture, developing countries are increasingly stressing to obtain a better portion of the benefits and wealth that the globalization is creating. There should be a system of TK protection in which TK holders and all of who have let it pass on and grow through centuries are properly acknowledged and rewarded. Although this principle seems to embody in the Benefit Sharing concept mandated by the international agreements as CBD and ITPGRFA[50], it does not only mean receiving economic or financial reward, but most of all, acknowledgement for the work TK holders have done, and bringing equity to a relationship that has been unjust and unequal.[51] To fulfill what this principle demands, South countries will probably have to change both discourses and ways to negotiate in the international system, focusing in what they have to offer for the future, instead of just keeping in claiming for the everlasting stealing of TK and genetic resources from developed countries. Although no one defends what have already happened, the effort should be put on how to advance to a better and more balanced relationship in which both result benefited.

Prior Informed Consent (PIC)

TK, which is held by a traditional community, should not be accessed, recorded, used or commercialized without the prior informed consent of traditional knowledge holders. This broad principle is implied in the provisions of international legal instruments,[52] implemented in most of the national TK protection measures developed so far, and proposed in several documents. PIC concerning TK is also a common feature of laws governing access to genetic resources, and its application has been further elaborated in the Bonn Guidelines established under the CBD[53].

Avoidance of Bio-piracy

From the perspective of the South countries, instead of vesting IPR's on TK, the major points to be reached by any TK protection system is to prevent misappropriation as well as to ensure benefit sharing. This is the central mandate of the CBD and claims that TRIP's harmonizes with such frame have emerged. For instance, from India's perspective, it should be added to TRIP's a disposition is needed ruling out patents inconsistent with Article 15 of CBD, which must not be granted. As seen above, prior informed consent (PIC) and sharing of benefit arising from commercial use with the country of origin of the material are required.[54] In this regard, it has also been argued that improving the information available to patent offices for examination of novelty and inventive step can help to prevent the granting of patents that unduly cover TK. However, the US patent law section 102 establishes that only written published information in the US or another country is not patentable, which is not the case of TK in most of cases, so such a disposition will not render useful in that country. Also, although this public availability may work as deterrent to improperly obtain patents, it has to be taken into account that making pieces of TK public can thwart –by losing priority for novelty- the granting of IPR's that might allow benefit-sharing experiences for TK holders.

Preservation of traditional lifestyles

Protection of TK has also been seen as generating a complex framework able to allow keeping long-standing and ancestral practices and knowledge that embodies traditional life styles. This sort of protection is radically different from the notion utilized by IPR's but it central as a component of the right to self-identification and also condition for the continuous existence of indigenous and traditional peoples. In sum, we are talking about the cultural heritage of humanity. Some have argued that vesting IPR's or other forms of property for indigenous communities on such knowledge will contribute to its respect and economics returns, while other have contested that approach stressing that converting previous public domain in property "will not save it, conserve it make people respect it or want to use it. Fencing off their knowledge does nothing to protect it from being more eroded, undermined, or ignored or at risk of being lost".[55]

Conservation

Along with equity, any system has to take care of TK for biodiversity conservation aims, taking the necessary steps to allow a sustainable exploitation of these resources. If financial considerations were the only ones that drive the decision of which crops are to be developed, then a serious damage may arise for keeping varieties that do not meet such

[50] See supra 1.1

[51] Tobin, 2004 (supra 1); Correa, 2001 (supra 16).

[52] The CBD Secretariat notes that the principle of PIC is "embedded in the wording of Article 8(j), whereby, subject to national legislation, the wider application of the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity should only occur 'with the approval and involvement of the holders of such knowledge, innovations and practices.'"

[53] See Section IV. C of the Bonn Guidelines

[54] See supra 1.1

[55] The Crucible Group, 2001, cited by Correa, 2001.

considerations, but are however essential to assure the conservation of the environment, a sustainable agriculture and food security.[56]

Promoting TK's use and development

As we have seen, this is a key component of the CBD core of principles. This is part of the proactive approach of the protection system: promotion of the use of TK is an important goal in itself. According Correa, "protection may be, in this context, a tool for facilitating access".[57] In the view of Drahos, some form of protection could be suitable to create the basis of trust required for the local/indigenous communities to part with their knowledge, and improve their position to obtain value from it.[58] This is how stimulus works in the economic and financial system: "if some rights were recognized, knowledge holders may be more prepared to provide access to their knowledge and, if fairly compensated, they will have more incentives to conserve it and ensure future access".[59] This is, at the end of the day, the old virtuous circle theory, fully applicable to the subject matter that occupies us. The process in which countries' policies and systems of TK protection advance in generating the basis for this virtuous circle to work is probably the quintessential one.

Participation of indigenous and local communities

Although this may be regarded just as a feature of the process of building the system instead of a principle by itself, it is too relevant to highlight its importance. No system will properly work if local and indigenous communities, the TK holders, do not actively participate in the drafting of policies and legislation that is intended to regulate what has to do with their lifestyle, using customary decision-making processes, laws and protocols as far as possible.[60] Almost all international for a, as well as the doctrine of the main authors that have addressed TK, have remarked the importance of this participation. Indigenous communities that are TK holders are entitled to this, according to OIT Convention # 169[61] which has made this participation mandatory[62]. In the Chilean case, such participation has been called for in the Ley de Bases Indigenas (Law of Indigenous Basis), which mandates that indigenous peoples acknowledged by that Law will be asked to express their opinions in every matter related with cultural heritage[63]. An interesting view about participation of indigenous peoples not only in expressing opinions to draft legislation on TK, but also in the negotiation of agreements with alien organizations users of genetic resources and TK, can be found in Peru during the last decade, and lessons about this participation process as a fundamental one can be drawn from that experience.[64]

As we have seen, the protection of TK is not an end by itself, but a source of means to achieve different objectives suitable for different stakeholders. These objectives are not mutually exclusive but rather complementary to each other. WIPO has come up with the following classification[65], drawn from the TK protection systems drafted recently by some of the leading countries, which may also provide light to policy makers and legislators:

(a) Objectives related directly to TK and TK holders:

- To create an appropriate system for access to TK;[66]
- To ensure fair and equitable benefit-sharing for TK;[67]
- To promote respect, preservation, wider application and development of TK;[68]
- To provide mechanisms for the enforcement of rights of TK holders;[69]
- To improve the quality of TK-based products and remove low quality traditional medicine from the market;[70]

(b) Objectives related to biodiversity and genetic resource policy:

- To promote the conservation and sustainable use of biological resources and associated TK;[71]

[56] Correa, 2001 and IPR's Commission Final Report

[57] Correa, 2001

[58] Peter Drahos, "Indigenous knowledge and the duties of intellectual property owners". Intellectual Property Journal, 11, August 1997

[59] Correa, 2001

[60] See below 3.4.2

[61] OIT Convention # 169, Art. 6.

[62] It has been ratified by 18 countries so far. Chile has not ratified yet.

[63] Ley de Bases Indigenas, Art. 34.

[64] See Tobin and Swiderska, 2002.

[65] Wipo, TK Policy and Legal Options, 2004.

[66] Laws of the African Union, Brazil, Costa Rica, Peru.

[67] Laws of the African Union, Brazil, Costa Rica, Indian Biological Diversity Act of 2002, Peru. See also Objective (2) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

[68] Laws of Peru and Portugal. See also Objective (1) of the six objectives of TK protection proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

[69] African Model Law.

[70] Multiple *sui generis* administrative regulations of China.

– To promote the legal safeguarding and transfer of genetic resources associated with TK;[72]

(c) Objectives related to indigenous peoples rights:

– To promote development of indigenous peoples and local communities;[73]
– To recognize, respect and promote the rights of indigenous peoples and local communities;[74]

(d) Objectives related to sustainable development and capacity building:

– To enhance scientific capacity at the national and local levels;[75]
– To promote the transfer of technologies which make use of TK and associated genetic resources;[76]

(e) Objectives related to innovation promotion:

– To promote and recognize innovation based on TK;[77]
– To promote the development of Native arts and crafts.[78]

3.4.2. Legal approaches, doctrines and tools

After having reviewed the main principles that any policy should contemplate, it is important to understand that they need to flow to the legislation through diverse legal approaches and tools. The main doctrines that have been used so far in TK protection systems are[79]:

(a) The grant of exclusive property rights for TK: a useful tool to protect some forms of TK is the creation of property rights, typically regarding those that are susceptible of misappropriation. Normally, they allow preventing others from certain use of the protected TK. For suitable consideration in TK protection systems, it is important to make clear that such rights entail the chance of being communally or collectively held. This approach may include:

(i) The use of existing forms of broadly known IP rights;

(ii) The use of modified, adapted or extended forms of IP rights;

(iii) The use *of sui generis* measures granting newly defined exclusive property rights;

(b) The application of the principle of prior informed consent: this approach is one of the manifestations of the equity principle and grants TK holders the right for prior informed consent (PIC) for the use, reproduction or commercial exploitation of their TK, as well as benefit sharing arrangements as a condition of access. Usually, measures applying the PIC principle to TK are part of a regime regulating access to genetic or biological resources;

(c) A compensatory liability approach: It provides some form of financial equitable retribution or remuneration to compensate TK holders when IP rights are absent and their TK is used. For instance, the recently passed *sui generis* law of Peru contemplates an approach like this, 'in cases where the collective knowledge has passed into the public domain within the previous 20 years,' in which case a payment is made into a common fund based on "a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge."[80] This is found in some national copyright and related rights systems, such as compulsory licensing arrangements for certain public uses of musical works.[81]

(d) An unfair competition approach*:* This is a long-standing and traditional tool to handle misuse. While the repression of unfair competition has been recognized since 1900 as an object of industrial property protection under the Paris Convention[82], it does not grant exclusive rights over intangible property to the right holder. The suppression of unfair competition and misleading or deceptive trade practices through the application of a cluster of principles such as truth-in-advertising, the protection of confidentiality, unjust enrichment, and passing off. It has been discussed and used as a suitable tool for *sui generis* systems of TK protection, which supplements the grant of exclusive rights and the application of PIC for TK subject matter.[83] This is the case, for example, in several *sui generis*

[71] African Model Law and the Biological Diversity Act of India. See also Objective (6) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

[72] Law of Portugal.

[73] Law of Peru. See also Objective (5) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

[74] Laws of the African Union, Peru and the Philippines Indigenous Peoples Rights Act (1997).

[75] African Model Law and the law of Peru.

[76] Provisional measure of Brazil.

[77] Laws of China and Costa Rica. See also Objective (3) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

[78] S*ui generis* measures of the United States of America, in particular the Indian Arts and Crafts Act of 1990.

[79] WIPO, TK Policy and Legal Options, 2004

[80] See WIPO/GRTKF/IC/5/INF/2, Annex II, page 14.

[81] WIPO, TK Policy and Legal Options, 2004

[82] See Art.1(2) and Art.10*bis*, Paris Convention.

[83] Crf. Dennis S. Karjala, Biotechnology Patents and Indigenous Peoples, 2007, in Intellectual Property Managements in Health and

measures, which apply a truth-in-advertising approach to the marketing of indigenous craft products[84]. The courts have also applied general unfair competition laws.

(e) The recognition of customary law*:* dispositions that govern how knowledge is generated, maintained and transmitted within the community is usually rooted in customary laws and protocols which play a key role the recognition and protection of TK *for* Indigenous and local communities. TK protection should be based on and taking them into account. Not only conventional IP law, but also sui generis system developed so far, has recognized elements of such customary law within a broader framework of protection.

It is worth noting that considerable overlap between these different approaches can exist, and, of course, the boundaries between them are not precisely defined. However, they are still useful characterizations of the main general possibilities that have been used so far. Most existing *sui generis* systems combine at least two of these legal concepts, as WIPO points out[85]. For example, some *sui generis* protection laws for TK regulate access and benefit-sharing for a broad range of TK and also provide for the grant of exclusive rights over a more confined span of TK.[86] According to WIPO, "a compulsory liability regime or PIC regime (setting a rate of compensation for use of protected TK) could be combined with a right to exclude culturally offensive or degrading uses altogether. Customary law could be used in conjunction with any of the other doctrines to determine questions of ownership, sharing of benefits within the community, nature and degree of damages and other remedies, and means of dispute settlement".[87]

IV Conclusion and final thoughts

The earth belongs to us all and we all need to use its natural resources to survive. This must be done in a sustainable and balanced way by developed, developing and least developed countries. Access to genetic resources and TK is essential to continue to fight hunger and diseases. CBD and ITPGRFA, with broad participation of countries all over the world, have provided broad basis for such a scheme, advocating for equity and benefit sharing.

Countries in the South, and in a good portion in Latin America, and its poor communities are holders of a natural richness that has to be exploited according to such principles in a process that needs to be bolstered. Countries in the North have the scientific and technological capacity. Both of them need to partner under equitable conditions to endeavor projects that allow them to advance in innovation processes and to obtain the best for the human kind.

Decision makers in developing and least developed countries have a fundamental duty: to generate national policies and legislations that harmonize current legal schemes to the international principles set forth by CBD, ITPGRFA and some other agreements, as well as have them binding in each country, generating better conditions to negotiate in the international arena. A few countries in Latin America has been advancing in the process, as Brazil, Mexico, Costa Rica, Peru, Ecuador, Colombia, Nicaragua. There are some other countries in Asia and Africa that have important experiences in drafting policies and legislation, as highlighted before.

Chile urgently needs to align its process to these other countries. Endemic richness of genetic resources, plenty of ancestral TK practices, as well as the current carrying out of R+D projects associated to them have set conditions to focus on the matter in a more consistent way than previous attempts. Decision makers should allocate time and resources to generate a national policy and legislation on the field, broadly accepted by the main stakeholders as well as by all the interested parties.

Decision makers will face tough challenges. Great effort should be put on having the indigenous communities in the table of negotiation: its participation is called for by current and binding national laws and international regulations and should be properly managed. Sacred legal institutions, as ownership rights, will have to be scrutinized to properly adequate them to the international binding agreements on access to genetic resources.

Capacity building is critical for all the sectors involved in the process, but mostly for decision makers and public officers in charge of providing crucial information for the success of the process, as well as for the indigenous communities in order to have a fair and symmetrical negotiation. Universities and technological centers need to advance their agendas to continue to contribute to improve our national scientific and technological ability and to obtain fairer and better deals with developed world entities: awareness of the existence of

Agriculture Innovation: A Handbook of Best Practices (eds. A Kratigger, RT Mahoney, L Nelsen, et al.). MIHR:Oxford, UK, and PIPRA:Davis, USA.

[84] See, for example, the Indian Arts and Crafts Act of 1990 of the United States of America.

[85] WIPO, TK Policy and Legal Options, 2004

[86] See African Model Legislation of 2000; Provisional Measure No. 2186-16 of 2001 of Brazil; Law No. 7788 of 1998 on Biodiversity of Costa Rica; Biological Diversity Act of 2002 of India; Law No. 27,811 of 2002 of Peru; Indigenous Peoples' Rights Act of 1997 of the Philippines; and Decree Law No.118 of 2002 of Portugal.

[87] WIPO, TK Policy and Legal Options, 2004

several legal and contractual resources to handle the results of the R+D projects, understanding and using of them is fundamental to better achieve balanced conditions.

If decision makers do not exercise good judgment or, what is worse, simply continue to do nothing -as it would be expected by drafting policies and passing legislation on the matter- Chile will not be able to achieve the best conditions stemming from the use of our natural patrimony. Endeavoring a national process of defining such a policy and legislation, Chile should be able to reconcile conflicting interests, in a long term equation that allows both to bolster the quality of life of indigenous communities as well as to promote and strengthen activities consistent with the current strategy of development, based on adding value to our natural resources through innovation, for which international alliances are fundamental. Minds need to be raised from daily political fight and strategic goals and objectives need to emerge facing Chile's Bicentennial of Independence.