

I. General Background

The role of TK related to genetic resources in biotechnology development has become increasingly important. The benefits resulting from TK exploration can be tremendous. Due to its significant economic and healthcare contributions to society, the owners of TK should be sufficiently compensated for the use of their knowledge¹ and their rights should also be properly protected. Although some bioprospecting projects seek or try to seek prior informed consent from indigenous communities, that possess useful TK, and even in some cases develop limited benefits-sharing programs, in most cases local and indigenous communities are not adequately paid for the exploration and commercialization of their knowledge² and their rights are not protected. The issue is raising heated debate among the legal scholars all over the world in order to find a proper way to secure TK holders' rights.

A. Motivation

During the past several decades the TK related to healthcare and biotechnology has become exploited at an alarming rate³. Multinational pharmaceutical, cosmetic and chemical corporations turn their jaws to the biodiversity rich regions, full of GRs, indigenous communities and

¹ Gervais D., *The TRIPS Agreement: Drafting History and Analysis*, 3d ed. 785 et seq. (London: Sweet & Maxwell, December 2008), p.368.

² *Id.* at p.368.

³ Bastida-Munoz M.C., Patrick G.A., "Traditional Knowledge and Intellectual Property Rights: Beyond TRIPS Agreements and Intellectual Property Chapters of FTAS" (2006) 14 *Michigan State Journal of International Law* 259.

related TK. These corporations use GRs and related TK to invent new drugs and other products, patent them and enjoy profits generated from selling them on the open market without any reference to the origin of the idea, or any equitable compensation to TK holders, therefore being accused in biopiracy - misappropriation of TK by multinational corporations.

For example, French fashion house *Yves St. Laurent* for years had been using extract of *ilang-ilang* flower, imported from the Philippines, to produce one of its perfumes. *Ilang-ilang* cultivated in the Philippines was found to be of the highest quality in the Southeastern Asia. In 1990s *Yves St. Laurent* started growing the flower on its own plantations in Africa, stopped importing it from the Philippines, and patented its perfume formula based on the native Filipino species⁴.

The similar case happened with *plao-noi* – a healing plant that has been recorded in Thailand’s traditional palm leaf books for centuries. In 1975, a team of researchers from *Sankyo Co. Ltd.* (now Daiichi Sankyo Inc.), one of the largest pharmaceutical companies in Japan, collected samples of *plao-noi*, extracted one of its active ingredients, and applied for a patent. Later the company started cultivating more than 1,000 ha of *plao-noi* in Thailand and sold it as tablets to treat ulcers, earning millions

⁴ Subbiah S., “Reaping What They Sow: Basmati Rice Controversy and Strategies for Protecting Traditional Knowledge” (2004) 27:2 *Boston College International & Comparative Law Review* 529. Available at <http://www.bc.edu/dam/files/schools/law/lawreviews/journals/bcicl/27_2/12_FMS.htm> [last accessed on July 2011].

of dollars⁵.

Another example of biopiracy is patenting by Japanese company *Ito En Ltd.* the medicinal properties of the *banaba* plant from the Philippines, a well-known herbal medicine widely used by local traditional healers to treat fever, diarrhea, and diabetes and well documented in national literature⁶.

Similarly, the University of Mississippi Medical Centre, Jackson, U.S. sought a U.S. patent for *turmeric*, a plant-based product widely known in India for cooking and medicine⁷. Cromak Research Inc., based in New Jersey sought to patent the properties of the *karela* plant, whose juice is considered a purifier and affords various medicinal benefits⁸. Moreover in some cases after getting patent rights over drugs, derived from some traditional knowledge or technique, a company prohibits the usage of this knowledge by an indigenous community⁹.

For instance, in the U.S.-based W.R. Grace case, a U.S. agricultural chemical company obtained patent rights to the active ingredient of the *neem tree*, which had been used for centuries in India in medicinal and

⁵ Quijano R., Zamora O., «Biopiracy, TRIPS and the Patenting of Asia's Rice Bowl», report, 25 May 1998, available at: <http://www.grain.org/article/entries/27-biopiracy-trips-and-the-patenting-of-asia-s-rice-bowl#1> [last accessed on December 2011].

⁶ *Id.*

⁷ Subbiah, *supra* note 4.

⁸ *Id.*

⁹ Such behavior may also mislead consumers and create unfair competition. Most of the consumers don't have even any idea that many valuable medicinal products were derived from the plants with the help of TK or even "stolen" from indigenous communities

ceremonial ways, and tried to stop Indian manufacturers to produce *neem tree* value-added products¹⁰.

Cactus Hoodia, native to the Kalahari Desert in South Africa and used by local tribe San to minimize hunger and thirst during the long hunting periods in the desert, attracted South African researchers who discovered a unique property of the plant – a rapid weight loss without any apparent negative side effects. The scientists patented the biologically active molecule and sold out the rights over Hoodia. Eventually the patent was purchased by *Pfizer Inc.* for \$21 million¹¹. The San people not only didn't benefit from the exploration of their TK, but even didn't know about the bioprospecting and patenting of Hoodia's properties. In fact, they have lost the opportunity to profit from exploiting their traditional knowledge, or even to decide whether and how to share it with the world.

The cases, introduced above, and numerous other evidences of biopiracies inspired us in conducting the present research in order to investigate the problem and find the suitable solution that will protect both the interests of TK holders – indigenous and local communities – and bioprospectors – pharmaceutical companies.

¹⁰ Subbiah, *supra* note 4.

¹¹ Barnett A., "In Africa the Hoodia Cactus Keeps Men Alive: Now Its Secret Is 'Stolen' to Make Us Thin", *the Guardian*, June 17, 2001 . Available at: <http://www.guardian.co.uk/world/2001/jun/17/internationaleducationnews.businessofresearch/print> [last accessed on December 2011]

B. Scope and Limitations

The dissertation is focusing mostly on TK, usually medicinal, attributed to laboratory research itself, having scientific and commercial value for the private entities and institutions and undisclosed to non-indigenous world.

1. The nature and definition of TK

Traditional knowledge of indigenous communities in people's minds is usually associated with artworks, handicrafts and other products of folklore. But this is just part of a whole bunch of TK elements. Scholars give different definitions of traditional knowledge due to the complexity of TK and numerous forms it can take: both tangible (expressions of folklore) and intangible (ideas, techniques, practices, information in such fields as agriculture, medicine and healthcare, pharmaceuticals, biotechnology, environmental protection, etc). *'The body of traditional knowledge is never static but rather dynamic in its shape and substance.'*¹² Marko Berglund identifies TK as *'an integral part of the indigenous and traditional communities from which it originates'*¹³. Professor Dutfield stresses the scientific character of TK, saying: *'...one shouldn't conclude that TK is inherently unscientific...TK, especially related to medicinal*

¹² Balick M.J., 'Traditional Knowledge: Lessons from the Past, Lessons for the Future', in C. McManis (ed.), *Biodiversity & the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (2007), 289.

¹³ Berglund M., "The Protection of Traditional Knowledge Related to Genetic Resources: The Case for a Modified Patent Application Procedure", 2 (2) *Journal of Law, Technology & Society* (2005), 133-276, available at <http://www.law.ed.ac.uk/ahrc/script-ed/vol2-2/TK.pdf> last accessed 12.08.2011).

knowledge, is not less scientific than western forms of knowledge. It can be new and innovative'.¹⁴ "Tradition" merely means the way it is preserved.

TK, being an integrate part of communal customs and traditions, develops and maintains the life of indigenous people. Professor Dutfield notices that "some indigenous and local communities depend on traditional knowledge for their livelihoods and well-being, as well as to sustainably manage and exploit their local ecosystems"¹⁵.

Traditional knowledge has "unfixed" character¹⁶: for indigenous people there has never been a need to commercially trade their knowledge inside community, that is why they seldom codify TK in written form, but rather pass it orally or record it in ways different from accepted Western scientific conception.

2. The importance and value of TK for bioprospectors

According to the World Health Organization up to 80% of the world's population relies on traditional medicine¹⁷.

Recently, it has been quite common for private companies and research institutions engaging in bioprospecting to sign so called "bioprospecting agreements" with the GRs provider: national or local government

¹⁴ Dutfield G., *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, (London: Earthscan, 2004), at 91-95.

¹⁵ *Id.* at 97-100.

¹⁶ Arezzo E., "Struggling Around the "Natural" Divide: the Protection of Tangible and Intangible Indigenous Property", 25 (1) *Cardozo Arts and Entertainment Law Journal*, (2007).

¹⁷ Erstling J., "Using Patents to Protect Traditional Knowledge", 15 *Texas Wesleyan Law Review* 295, (2009).

authorities. Such agreements include different conditions and terms of bioprospecting: the prior informed consent (PIC), volume, rewards, etc. But before gaining permission for the access, it's better for the private entities or institutions to get the information about the future practical and commercial value of genetic material they are going to research. It's well-known that the probability of success in bioprospecting is very low. Scientists sometimes use thousands of samples in order to get a result¹⁸. Such information, for example, regarding the potential medical use of a plant, is available from indigenous communities living in the places where genetic material is collected, and is also called traditional knowledge. It has already been calculated that medicinal traditional knowledge decreases research and production costs by 40% or by \$200 million a year¹⁹. Thereby TK solves market failure problem by providing incentives to invest in potential paths of research.

Therefore, for bioprospectors, traditional knowledge is valuable, because it helps to assess risks and benefits of the future project, to lower high risk, and to increase the probability of the future product success on the market.

3. TK: public domain vs. communal ownership

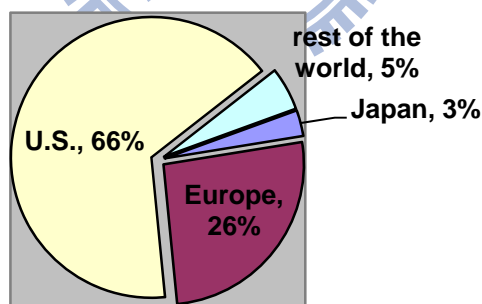
Anthropology and other social sciences describe GRs and associated TK as a common heritage reflected in the common property regimes. Like the common property, common heritage implies open access, but

¹⁸ Coughlin Jr., "Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity", 31 (2) *Columbia Journal of Transnational Law* (1993), at337-375.

¹⁹ Bastida-Munoz &Patrick, *supra* note 3.

whereas private property regimes often imply “club goods” that are openly accessible only to members, common heritage for GRs tends to involve fuzzy and permeable boundaries and control. The problem is that indigenous peoples’ ownership over TK is not recognized worldwide. Though national laws of some countries with rich GRs and TK such as Brazil, Panama or Peru have recognized indigenous communities’ IPRs over TK,²⁰ for bioprospectors, traditional knowledge is a common property²¹. The key issue is that most of the patents especially in pharmaceutical field, are issued in the U.S. (see fig.1), (see Appendix tables 1 and 2), therefore it is the U.S. patent system that “calls the tune” and makes traditional knowledge entirely vulnerable to exploitation by the enterprise world.

Figure 1. World market share of new medicines launched during the period 2004-2008



²⁰ See the Brazilian Provisional Measure On Access to Genetic Resources and Traditional Knowledge No. 2.186-16, of August 23, 2001 (Provisional Measure, 2001); the Panamanian Law No. 20 of 26 June 2000, ‘On the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge’; and the Peruvian Law No. 27811 ‘Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources’, published on August 10, 2002, respectively.

²¹ Bratspies R., “The New Discovery Doctrine: Some Thoughts on Property Rights and Traditional Knowledge”, 31 *American Indian Law Review* (2007), at 315.

Source: IMS Health MIDAS MAT December 2008

According to the principles of the Western IPRs laws, TK belongs to the public domain and can be freely used without prior consent or compensation to its holders. Though being in the public domain TK, nevertheless, doesn't constitute a prior art in the United States. Thus according to the U.S. patent system (35 U.S.C. § 102) the patent can be deemed invalid on the ground of anticipation only if it is used by others or is in the public use in the United States, or patented or described in a printed publication in the United States or in a foreign country. Traditional knowledge is usually not formally documented, therefore no matter how well-known the indigenous knowledge is, as long as it is outside the U. S. and is not in a written form, foreign companies are eligible to apply for the U.S. patent containing TK.

C. Statement of problems and issues

1. Why protect traditional knowledge?

As long as western companies do not bear any costs for the utilization of traditional knowledge, TK represents a positive externality²². Furthermore, creation and preservation of TK by indigenous communities are not driven by the incentives of a market economy, the knowledge is usually shared within the community. By obtaining exclusive rights over traditional knowledge countries bioprospectors damage the economy of the biodiversity rich countries as they deprive countries biosuppliers the

²² Arezzo, *supra* note 16.

opportunity to trade with pharmaceutical and biotech companies and make profits²³. Such TK-based products as plant-based medicines, cosmetics, health products constitute the value-added of TK-rich countries and could be the source of export revenue²⁴.

Misappropriation of TK is closely connected with the exploitation of biological resources. There are serious environmental risks associated with unregulated and unmonitored taking of biodiversity and collective indigenous knowledge²⁵.

If the “bad patenting” is not stopped, a bigger problem will occur soon: if the TK is exploited and patented by too many bioprospectors the phenomenon of “a tragedy of anti-commons” may occur²⁶. Competing patent rights could actually prevent useful and affordable medical and cosmetic products from reaching the marketplace.

On the other hand, without providing western companies with acceptable conditions of the access to TK, biotechnological and pharmaceutical companies would need enormous resources to obtain necessary results, passing the costs on consumers²⁷.

Biopiracy has raised strong confrontations between developing (biosuppliers) and developed (bioprospectors) countries. To prevent “bad patenting” of traditional medicinal knowledge, international community

²³ *Id.*

²⁴ Erstling, *supra* note 17.

²⁵ Arezzo, *supra* note 16

²⁶ *Id.*

²⁷ *Id.*

has been proposing different solutions. The most debatable one is to amend Trade-Related Aspects of Intellectual Property Rights (TRIPS) by including new disclosure requirements in the patent applications: 1) disclose the country of source and origin of the TK; 2) show formal consent from the source of knowledge. Most of the developed world, especially multinational pharmaceutical corporations, don't support this initiative on the ground that the cost of transforming traditional medicinal knowledge into a marketable drug requires huge investments (average \$300-\$500 million) and a long period of time (average 10 years), but the profits are not guaranteed²⁸.

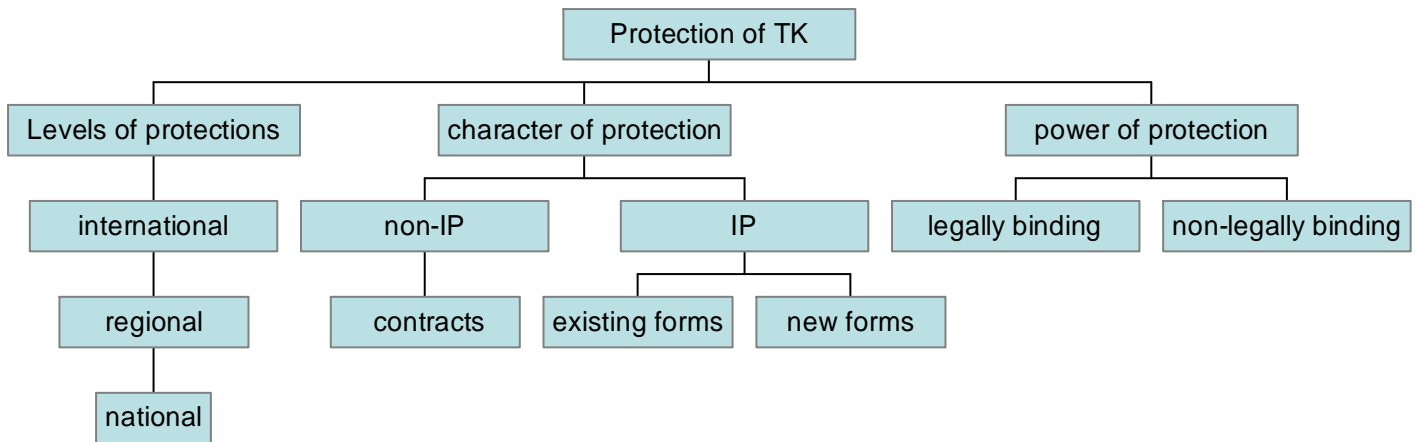
The international debate about the protection of TK related to GRs has not yet come up to any compromise. There is still no operating binding international agreement that provides effective protective measures. A solution that satisfies the interests of both biosuppliers and bioprospectors is needed.

2. Assessment of existing legal instruments to TK protection

Theoretically and practically there are various ways to protect TK depending on its character (type) and the legal system of the country where the TK is to be protected.

²⁸ Dwyer L., 'Biopiracy, Trade, And Sustainable Development' 19 Colorado Journal of International Environmental Law and Policy 219, (2008).

Figure 2. Measures for the Protection of TK



*The information for the chart was taken from WIPO/GRTKF/IC/2/5

The protection can be performed either through the existing legal methods, or by means of creating new legal instruments or a mix of them. The level of protection can be international, regional, or national.

The international legislature in respect of indigenous peoples' rights and TK protection is already rich and diverse. The main legal frameworks are: the Convention on Biological Diversity (CBD) (1993) that covers such TK related issues as prior informed consent (PIC), access and equitable benefit-sharing (ABS) for the purpose of sustainable use and conservation of GRs²⁹; the FAO' International Treaty on Plant Genetic Resources for Food and Agriculture (2001); the UN Declaration on the Rights of Indigenous People (2007), the WIPO Intergovernmental Committee on

²⁹ These issues are mostly contained in Article 8(j), Article 18.4 of the Convention on Biological Diversity, and also in CBD Bonn Guidelines on Access to Genetic Resources and Benefit Sharing (ABS) (2002). The full text of the Convention is available at <http://www.biodiv.org/doc/legal/cbd-en.pdf> (last accessed 29.09.2011). Bonn Guidelines is available at <http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> (last accessed 29.09.2011).

Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC)(2001) and its Draft Provisions on Traditional Cultural Expressions/Folklore and Traditional Knowledge.

According to the CBD, GRs are under national sovereignty, but the CBD also provides that the member state should take into consideration the rights of indigenous communities, who have knowledge on how to preserve and use biodiversity in a sustainable way.

The global frameworks mentioned above have a minor obligatory character, and still need to be adopted and ‘digested’ by national legal systems. They include general guidance to the national policies of the signatories and lack specific instruments for the protection of indigenous peoples’ rights over TK and their enforcement.

An example of the regional level of TK protection is the Common Regime on Access to Genetic Resources, and the Common Intellectual Property regime adopted by the members of the Andean Community³⁰. These regimes enabled Bolivia, Colombia, Ecuador and Peru to build a property regime of TK protection that requires the consent of indigenous communities and a plan for equitable profit sharing before any patent can be claimed for a product derived from GRs or TK.

³⁰ Andean Community/Decision 391: Common Regime on Access to Genetic Resources (July 2, 1996), <http://www.comunidadandina.org/ingles/normativa/d391e.htm> [last accessed on December 2011].; Andean Community: Decision 486 (Sept. 14, 2000), <http://www.comunidadandina.org/ingles/normativa/d486e.htm> [last accessed on December 2011].

On the national level, the protection of TK varies from country to country. Now more and more countries have created their own TK protection systems. There are two ways of TK protection under national laws: as a form of property by establishing special laws, regulating TK access, use and benefit sharing from its use; and by means of using the existing national IPRs laws³¹.

For example, countries using the first method of TK protection include Peru, Costa Rica, Brazil, India, etc. Peru and Costa Rica have biodiversity laws that protect TK as the indigenous peoples' IP, with practices and innovations belonging to the whole community. The government of these countries created special databases to store TK, to protect its holders and to guarantee equitable benefit sharing. Indigenous communities get benefits arising not only from TK usage but also from the access to genetic resources. In Brazil, access to TK is carried out through material transfer agreements (MTAs) in which the researcher, according to national access legislation, has to disclose certain information. In this model, the government plays a significant role in the protection of the rights of TK holders.

Thus, in the first method mentioned above, the success in the protection of TK considerably depends on the government's involvement and also on how well the indigenous people and their interests are represented by the government.

³¹ Lewis W.H., Ramani V., «Ethics and Practice in Ethnobiology: Analysis of the International Cooperative Biodiversity Group Project in Peru», in C. McManis (ed.), *Biodiversity & the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (2007), at 396.

The second method is not widely used as it is not easy to apply strictly developed intellectual property rights to the unspecified holistic traditional knowledge in general and genetic resources associated with TK in particular. Some scholars doubt that existing IP regimes are suitable for TK protection³².

A strong and executable national TK protection system is necessary and important in all senses. But in the age of globalization the international protection across countries is not of less importance.

The problem is that traditionally IP law remains within the competence of States' national jurisdiction with little interaction with international law. The existing relevant international law is not legally binding for the member-states, but rather constitutes a soft law: advice, recommendation and guidelines. Such hard law as the Agreement on Trade-Related Aspects of Intellectual Property Rights doesn't recognize property rights in TK. While the existing international and national tools alone can't provide adequate protection of rights of the TK holders worldwide and the workable obligatory mechanism is not established yet³³, such a non-IP

³² Dutfield, *supra* note 14.

³³ On 29 October 2010 the Conference of the Parties to the Convention on Biological Diversity adopted an international legally binding protocol on access to genetic resources and benefit-sharing—the Nagoya Protocol. The Protocol will be open for signature by Parties to the CBD until 1 February 2012. The Protocol covers genetic resources as well as associated TK, imposing the obligation of fair and equitable sharing of benefits from the utilization and commercialization of genetic resources and associated traditional knowledge with the contracting party providing GR and TK. Previously, there was no international legal obligation to ensure equitable sharing of benefits from using genetic resources and associated TK. The Nagoya Protocol requires user countries to introduce legal, administrative or policy measures to ensure compliance with the access and benefit-sharing law of provider countries. However, the Protocol has some limitations that reduce the scope for

instrument as contractual agreement can become a “golden mean” fitting both cases: whether parties are from the same country or not. Contractual agreements are not novel in transactions such as access to genetic resources and benefit sharing, for example the Merc-INBio agreement³⁴. Traditional knowledge has always been just part of such agreements, usually mentioned in prior informed consent, and indigenous people or their representatives have seldom become a rightful party. Nevertheless, while examining bioprospecting agreements few cases were found, in which TK holders acted as rightful members of the genetic resources and associated TK transfer. Contract models in the projects of the International Cooperative Biodiversity Group (ICBG) are good examples of how contractual agreements may properly protect both the interests of bioprospectors and, more importantly, TK holders as well. For example, such ICBG projects as the Peru-ICBG program (1994-1999), the Maya-ICBG (1998-2001) and the ICBG UIC–Vietnam–Laos (1998-2003) are characterized with high involvement of TK holders or their legal representatives into contractual agreements as a rightful party. Prior informed consent and associated measures are a mandatory part of all ICBG projects.

benefit-sharing with countries and communities. For example, it does not recognize the customary rights of communities or require the protection of rights over associated traditional resources. It also does not itself require the prior informed consent of indigenous or local communities, but requires countries to develop policy and legal measures for this, which will take some time (source: <http://biocultural.iied.org/policy/nagoya-protocol-access-genetic-resources-and-benefit-sharing> [last accessed on December 2011]).

³⁴ Coughlin, *supra* note 18.

D. Main Arguments

The thesis argues that private contractual arrangements may serve the interests of relevant stakeholders of TK and can largely become an alternative to other methods for TK protection whereas the workable international regime has not been established yet.

The thesis explores the strengths and weaknesses of using contracts for the protection of TK holders. Among the most significant advantages are the freedom of concluding contract and its flexibility. Thus, contract could become a very flexible instrument, fitting the characteristics of particular transaction. On the other hand, obviously, the approach has some limitations such as imbalance of bargaining powers between contracting parties and difficulty for enforcement, etc.

In order to overcome such drawback of contractual arrangement as unequal bargaining power it is argued that TK, undisclosed to non-indigenous world, could be treated as trade secret (know-how). The ownership ensures that indigenous peoples can engage with the state and third parties as active stakeholders rather than as passive beneficiaries.

E. Methodology and Theoretical Basis

The applied research tools include analysis and synthesis, empirical analysis such case study, abstracting, comparison, deduction, induction, conclusion by analogy.

The first and major argument of this work – using private contractual approach to the protection of TK – is based on the doctrine of contracts

and supported by the empirical analysis – case study. Several ICBG projects and concomitant contractual agreements are taken as an example of relatively integrated and successful scheme of collaboration between indigenous communities, research institutions and private entities. ICBG projects are characterized with high involvement of traditional knowledge holders or their legal representatives into contractual agreements as a rightful party. Prior informed consent and associated measures are a mandatory part of all ICBG projects.

The second argument – using property approach to TK (i.e. trade secret protection) in order to enhance the bargaining power of indigenous peoples – is supported by several modern economic theories of property. The first one is Jane Radin’s “personhood” property theory, which was derived from John Locke’s “natural right”³⁵ and Kant’s and Hegel’s imperative’s approach to property³⁶³⁷. According to Kant, when someone extends his will to a thing, he makes that thing a part of himself. Protection of property is thus intimately connected with protection of the human will. Locke's approach to a natural right to a thing arises out of labour, and though it does not require state sanction in order to be valid, should, however, be protected by the state.

³⁵ Locke J., *Two Treatises of Government* [1689] Peter Laslett (ed.), Cambridge: Cambridge University Press, 1988.

³⁶ Kant I., *The Metaphysics of Morals* [1797], Mary Gregor (trans.) Cambridge: Cambridge University Press, 1991.

³⁷ Hegel, G.W. F., *The Philosophy of Right* [1821], T.M. Knox (trans.), Cambridge: Cambridge University Press, 1967.

Modern economic theories based on cost-benefit analysis such as those described by Merrill&Smith³⁸ and Hansmann&Kraakman³⁹ justify property on the ground that there must be an initial allocation to allow the market to operate and on the ground that individual property rights minimize transaction costs. Such approach is derived from the tradition of Bentham⁴⁰ and Mill⁴¹.

The research also applies such theories as the Garrett Hardin's «tragedy of the commons»⁴² to address the issue of possible over-exploration of TK and associated biological resources treated as common heritage in case of their unauthorized, unrewarded, unmonitored taking; the Michael Heller's «tragedy of anticommons»⁴³ illustrates the problem of underutilization of indigenous knowledge when too many exclusive rights are granted over each piece of traditional knowledge, preventing the very same indigenous peoples from using their own intangible scientific heritage; the Carol Rose's⁴⁴ and Lee Ann Fennell's⁴⁵ «limited common

³⁸ Smith H., Merrill T., “Optimal Standardization in the Law of Property: The Numerus Clausus Principle”, *Yale Law Journal*, 110 (2000).

³⁹ Hansmann H., Kraakman R., “Property, Contract, and Verification: the Numerus Clausus Problem and the Divisibility of Rights”, 31:2 *Journal of Legal Studies* 373 (2002).

⁴⁰ Bentham J., «*The Theory of Legislation*» [1802], C.K. Ogden (ed.), London: Kegan Paul, Trench, Trubner & Co., 1931.

⁴¹ Mill J. S., «*Principles of Political Economy*» [1848], Jonathan Riley (ed.), Oxford: Oxford University Press, 1994.

⁴² Hardin G., «The Tragedy of the Commons», 16 *Science* 3859, pp. 1243-1248, 1968

⁴³ Heller M., «*The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*», 111 *Harvard Law Review* 621-688 (1998).

⁴⁴ Rose C., “The Several Features of Property: Of Cyberspace and Folk Tales. Emission Trades and Ecosystems” 83 *Minnesota Law Review* 129 (1998).

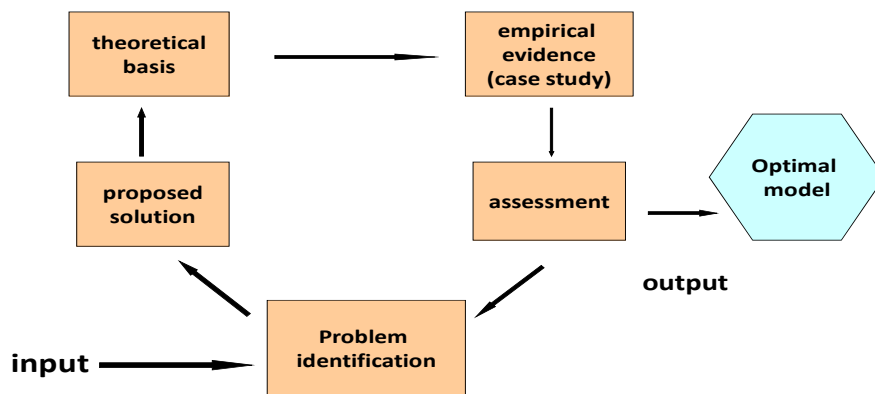
⁴⁵ Fennell L.A., “Commons, Anticommons, Semicommons”, in K. Ayotte, H.E. Smith (eds), *Research Handbook on the Economics of Property Law*. (Cheltenham: Edward Elgar, 2010).

property» (LCP) theory justifies that western concepts of “individual”, “private”, “personal” right can fit the communally developed and preserved knowledge.

F. Conceptual and research model

The model of the research process is designed by the five blocks that are consecutive phases of the study (see **Fig.3**).

Figure 3. Conceptual and research model



The first step is the problem identification: from fuzzy sets of facts of TK misappropriation into a coherent statement of the question: biopiracy and its consequences. The second level is making a supposition of the possible suitable solution: private contractual arrangements. At the third and fourth stage of the research process the proposed hypothesis are supported with existing legal and economic theories and empirical studies. Finally the suggested solution of biopiracy is assessed and evaluated. The discovered drawbacks of using contracts such as the imbalance of bargaining powers of the contracting parties can be resolved by treating

undisclosed to non-indigenous world TK as trade-secret. The assessment of the proposed solution is carried out according to the same block-scheme. The output of the research is a proposal of an optimal model of TK licensing agreement.

G. Research objectives

This research has a broad range of objectives.

1. The first objective is to use theoretically and empirically derived knowledge to augment the existing body of anecdotal research information related to concurrent TK private contractual arrangements. There is no integral theoretical and empirical assessment of private contractual arrangement containing TK in the concurrent legal study. Therefore, the main purpose of the research is to develop better understanding of such instrument of TK protection as private contractual arrangements, scrutinize and assess private contractual arrangements.
2. Another objective is to confirm the applicability of private contractual arrangement for the TK protection at the international level. To analyze whether contract model may properly protect both the interests of bioprospectors and, more importantly, TK holders as well.
3. Finally, the research provides a practical mechanism of collaboration between interested parties, implementing optimal model of TK licensing agreement that would result in a greater balance of bargaining powers.

The main findings, conclusions and proposals may also be used by government agencies to develop position papers and recommendations to

solve the problem of biopiracy.

H. Structure

The thesis is divided into five parts

Part I gives the general background of the TK exploration and protection. It addresses the concept of TK and its high value both for indigenous people and non-indigenous world. The present part scrutinizes the problem of biopiracy and the current international debate about this problem. The chapter explores the existing legal instruments of the TK protection on the international, national and regional levels.

Part II will analyze private contractual arrangements in bioprospecting process. It will explore the theoretical background of using contractual agreements, addressing the general structure and main features of the ICBG projects. The chapter, then, will discuss three contractual ICBG agreements, including Peru-ICBG, Maya-ICBG and UIC-Vietnam-Laos ICBG, thoroughly examining each mechanism and identifying advantages and flaws of contractual arrangements with regard to TK protection. It has been recognized that one of the main drawback is the imbalance of bargaining powers between contracting parties. It is interesting to discuss the ways of enhancing imbalance of bargaining powers between contracting parties.

Part III argues that in order to overcome imbalance of bargaining powers, indigenous people should be granted some IPRs over their TK. Based on the indivisibility and interdependence of the TK and personhood, the present part aims to analyze the property approach to TK

protection as opposed to treating TK as commons and applying defensive protection. It is argued that among all existing forms of IPRs trade secret (know-how) seems to be the most applicable for the indigenous knowledge related to genetic resources. Trade secrets are established through common law and to protect them, one must utilize the legal options provided by contract law and tort law. Yet there are some shortcomings in applying trade secret over holistic TK. Only the knowledge that has not been revealed to the non-indigenous world can enjoy this kind of IP protection. Trade secret refers to the information that has industrial or business value. But not only business sector is hunting for TK, many scientists and scientific institutions access or wish to access to traditional knowledge related to genetic resources.

The results and discussion are described in **Part IV** that contains an optimal legal mechanism of bioprospecting and a guideline of a TK licensing agreement.

Part V is the conclusion.

II. Using private contractual arrangement to protect the rights of indigenous peoples over traditional knowledge related to genetic resources: ICBG case study

A. Introduction

To ensure a fair benefit-sharing, based on mutually agreed terms, between TK users and holders, contracts are considered one of the major means to reach this goal⁴⁶.

Contractual agreements are not novel in transactions involving access to GRs and benefit sharing. The most famous and earliest case was the Merc-INBio agreement⁴⁷. TK has always been only part of such agreements - usually mentioned in PIC - or else it has been simply omitted. Indigenous peoples (or their representatives) have seldom become a party to such contracts. Still, the history of TK exploration has revealed several more or less successful cases, where TK holders acted as rightful members of the genetic resources and associated TK transfer.

The International Cooperative Biodiversity Group (ICBG) is an example of a workable and relatively successful model for bioprospecting

⁴⁶ Bates K., "A Penny For Your Thoughts: Private And Collective Contracting For Traditional Medicinal Knowledge Modeled on Bioprospecting Contracts in Costa Rica", 41 *Georgia Law Review* 961 (2007).

⁴⁷ Coughlin, *supra* note 18.

efforts.⁴⁸ The main goals of the ICBG are to examine the medicinal potential of the earth's biodiversity, to support its conservation and to promote human health and economic development⁴⁹ by means of collaboration assistance between the different parties involved. It also aims to enhance the efficiency of this cooperation for the mutual benefit of all parties. These parties include pharmaceutical companies and research entities on one side and TK (especially medicinal) holders on the other.

B. The main concepts of doctrine of contracts

One of the major advantages of choosing contracts to protect TK is, according to classical contract theory, its freedom. Contracting parties are flexible in “creating” their rights and obligations through a contract. Smith's “Atiyah's Introduction to the Law of Contract”⁵⁰ points out that the obligations in the law of contract are “self-imposed”: “...the law of obligations deals primarily with duties owed by individuals to other individuals, and these duties are generally enforceable only by the persons to whom they are owed”.⁵¹ The doctrine of contracts has known many reasons to enforce private agreements, the main reasons of which are: economic grounds – to increase the welfare of society; and moral

⁴⁸ Soejarto D.D. et al, “Bioprospecting Agreements: Cooperation Between the North and the South”, in IP HANDBOOK OF BEST PRACTICES, Chapter NO.16.5, BioThailand 2003 Proceedings, available at <http://www.iphandbook.org/> [last accessed on December 2011].

⁴⁹ Lewis&Ramani, *supra* note 31, at 400.

⁵⁰ Smith S.A., *Atiyah's Introduction to the Law of Contract*, (New York: Oxford University Press, 2005).

⁵¹ *Id*, at 1.

grounds – defendants have duties owed to the claimants to do what they are contracted to do, to remedy injustice caused by the defendant.

Historically the traditional or classical theory of contract law goes back to the eighteenth and nineteenth centuries⁵² when the lawmakers were mostly influenced by the laissez-faire philosophy which meant the state and the law shouldn't (or as little as possible) interfere with transactions between people⁵³. The judges didn't care about the fairness or the conformation of contracts with public interest. The role of the courts was merely to protect the parties from nonperforming. But little by little the society and lawmakers realized that such "unlimited" freedom of contracting has its reefs or externalities: fairness, fraud, duress, lack of choice, lack of understanding (need to be legally sophisticated to understand all clauses), etc. In the end of the nineteenth century the situation changed and starting from the 20th century there has been a tendency in legislation development to protect the weaker party. The contemporary period of the development of the contract theory started in 1980. Gordley in his book "The Philosophical Origins of Modern Contract Doctrine"⁵⁴ states that "systems of private law modelled on those of the West will govern nearly the entire world". Whereas the western legal systems, "common law" and "civil law", are much alike,

⁵² Before that period of time the paternalistic ideas were popular while enforcing rights and obligations arising from a contract.

⁵³ Smith, *supra* note 50, at 9.

⁵⁴ Gordley J., *The Philosophical Origins of Modern Contract Doctrine*, (Oxford University Press, 1991).

having a similar doctrinal structure which is based on similar legal concepts, there are two main trends now⁵⁵:

- reverse to the early nineteenth century freedom of contract principles when pro-market views dominated among the lawyers and economists;
- move away from the freedom of contracts (notion of morality).

The followers of the first trend tend to facilitate contracts more than protecting the weaker party, claiming that the parties to the contract enter into agreement only if they have benefit from it, and when each party gains something total social welfare increases.

The followers of the second trend argue that there is no ideal economy and people mostly behave irrationally, sometimes disadvantageously to themselves. Secondly, interventionist policies (default or compulsory terms) will make it easier to make contracts, helping to save time and expenses.

Though the supporters of the first trend stand for the “absolute freedom” of contracts, it doesn’t mean that they ignore such concepts as “fairness”. According to the classical theory there are two sides of fairness here: fairness in the process of making a contract and fairness in the outcome of a contract. Courts deal only with the second one. Smith in “Atiyah’s Introduction to the Law of contract”⁵⁶ compares making a contract with a game, where certain rules are set, and they are fair. If everybody plays

⁵⁵ Smith, *supra* note 50, at 16.

⁵⁶ *Id.* at 296.

according to these rules “there is very limited scope for any concept of a “unfair outcome”.” Of course, the participants of the game are different, have different skills and possess a different amount of information. But the rules just need to be applied properly and bargains to be voluntary and free. If each party to a contract is satisfied with the exchange, how can it be stated that the result is unfair? The law should respect the contract the two parties willingly made. All the rules and laws regarding enforceability of the contracts using fraud, misrepresentation, or protecting minors deal only with procedural fairness. No law or rule says that substantively unfair contracts are unenforceable. According to traditional law only limited relief will be provided in cases involving “cognitive” defects or “information asymmetries”. The court will not rule a contract unenforceable merely because the defendant did not understand (or even read) its terms, even when there is a lack of understanding, in the circumstances, entirely reasonable and perhaps even expected⁵⁷.

C. ICBG case-study

1. An overview of ICBG projects

The ICBG Program was established in 1992 by the National Institute of Health (NIH), the National Science Foundation (NSF) and the U.S. Agency for International Development (later replaced by the Department of Agriculture (USDA))⁵⁸ to run multidisciplinary projects addressing

⁵⁷ *Id.* at 297.

⁵⁸ McManis C.R., “Intellectual Property, Genetic Resources and Traditional Knowledge Protection: thinking Globally, Acting Locally”, 11 *Cardozo Journal of International and Comparative Law* 547 (2003).

drug development, biodiversity conservation, and economic growth⁵⁹. More than 12 projects in 18 countries of Asia, Africa and Latin America have been supported under the Program⁶⁰. Seven ICBGs (awards) are currently running⁶¹. The source of funding in ICBG projects can be from both the public and private sectors. Another essential goal of the Program is “to develop models for sustainable and equitable commercial use of biodiversity-rich ecosystems...”⁶².

The ICBG project usually involves a multinational pharmaceutical corporation, a nongovernmental organization, a research university, and collaborating partners of a source country (research institute, indigenous communities or their representatives)⁶³.

Current projects under the ICBG Program (both academic research and commercial drug development) are jointly funded by NIH, NSF, USDA and also two other governmental agencies: U.S. Department of Energy (DOE) and National Oceanic and Atmospheric Administration (NOAA)⁶⁴.

⁵⁹ Goals and other information regarding ICBG are available at the ICBG web site at <http://www.icbg.org/>.

⁶⁰ Rosenthal J., “Politics, Culture and Governance in the Development of Prior Informed Consent and Negotiated Agreements with Indigenous Communities”, in *BIODIVERSITY & THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE* 373-393 (Charles McManis ed., 2007).

⁶¹ Biodiversity Conservation and Drug Discovery in Madagascar (1993-present), ICBG: Training, Conservation and Drug Discovery Using Panamanian Microorganisms (1998-present), Bioactive Compounds from the Biodiversity of Vietnam and Laos (1998-present), Biodiversity Surveys in Indonesia and Discovery of Health and Energy Solutions (2008-present), etc, for more information see FIC web site at <http://www.fic.nih.gov/> [last accessed on December 2011].

⁶² *Id.*

⁶³ Asebey E.J., Kempenaar J.D., “Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention”, 28 *Vanderbilt Journal of Transnational Law* 703 (1995).

⁶⁴ See ICBG web site at http://www.icbg.org [last accessed on December 2011].

The administrative function is executed by the international component of NIH - John E. Fogarty International Center for Advanced Study in the Health Sciences (the leading agency in the ICBG Program)⁶⁵. The ICBGs call for collaboration among various public and private institutions including universities, environmental and community organizations, and pharmaceutical and biotech companies. This public-private conglomeration has currently been conducting collaborative multi-disciplinary research, with research being conducted in more than thirty different institutions in eight countries of Latin America, Africa, Asia, and the Pacific Islands⁶⁶.

The ICBG agencies, which utilize international collaborative models, bring together bioprospectors (research institutes and private biotechnology companies located both inside and outside the United States)⁶⁷ and biosuppliers (government authorities, research institutes and indigenous peoples) of biodiversity-rich countries (usually low and middle income countries)⁶⁸.

The ICBG has operating principles for assessing into GRs, treatment of IP and sharing of benefits associated with ICBG-sponsored research. According to these principles, the legal protection for any invention accrued during a project is achieved through the patent system, while the ICBG Program's agreements designate the terms of partnership between

⁶⁵ *Id.*

⁶⁶ See FIC web site at <http://www.fic.nih.gov/> [last accessed on December 2011].

⁶⁷ Soejarto et al, *supra* note 48.

⁶⁸ Bowels I.A., Kormos C.F., "The International Conservation Mandate of the United States Government", 11 *New York University Environmental Law Journal* 372 (2003).

collaborators as well as licensing of innovations and benefit sharing derived from such innovations⁶⁹. According to the ICBG policy, if TK is involved in drug discovery and the TK provider cannot be recognized as an inventor, the TK should be treated as know-how and the provider should be compensated for it⁷⁰.

According to the collaboration agreement, bioprospectors obtain access to biological material (including GRs) and are required to share benefits derived from the use of these resources and associated TK with biosuppliers and TK holders⁷¹. A critical point of the ICBG Program is “the development of ethically sound partnership among diverse collaborators”⁷². Before granting a funding award for a drug discovery project, a collaboration agreement is verified to comply with the principles of prior informed consent (PIC), access and benefit sharing (ABS) and a number of intellectual property rights issues⁷³.

Among other principles that collaborators should follow to be eligible for ICBG funding is “respect for and compliance with relevant national and international laws, conventions and other standards”⁷⁴. Thus, ICBG

⁶⁹ See ICBG web site at <http://www.icbg.org> [last accessed on December 2011].

⁷⁰ McManis, *supra* note 58.

⁷¹ The interest of ICBG in such projects is to help the U.S. research institutions and multinational pharmaceutical companies (many of them are based in the U.S.) to get access to genetic material and to move the majority of the sample screening to the United States. If most of the value-adding bioprospecting work is conducted outside the source-country, it has been argued that it is justifiable for the biosupplying partner of the ICBG project to receive a lower amount of royalties (i.e. 1%-2% in ICBG-Peru). See Asebey & Kempenaar, *supra* note 63.

⁷² Rosenthal, *supra* note 60, at 374.

⁷³ Rosenthal, *supra* note 60, at 377.

⁷⁴ *Id.*

licensing models support objectives of the Convention on Biological Diversity (CBD),⁷⁵ particularly with respect to PIC and access and equitable benefit-sharing for the purpose of sustainable use and conservation of genetic resources⁷⁶. These models are also designed to be in keeping with national and international laws. For instance, the Maya-ICBG project, in compliance with national laws, sought for and was granted an authorization from the competent governmental agencies. Article 87 of the Mexican federal law, “Ecological Equilibrium and Environmental Protection General Act” (effective March 1, 1988) (General Act),⁷⁷ which regulates collection of genetic resources and associated TK for scientific, commercial and biotechnological purposes, states that scientific collection of genetic resources and associated TK for non-biotechnological purposes requires authorization by the Secretariat of Environment and Natural Resources⁷⁸ and that the research results must be available to the public. If the resources are used for the purposes of

⁷⁵ *Id.*

⁷⁶ These issues are mostly contained in Article 8(j), Article 18.4, and also in CBD Bonn Guidelines on Access to Genetic Resources and Benefit Sharing (ABS) (2002), available at <http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> [last accessed on December 2011].

⁷⁷ Ley General del Equilibrio Ecológico y la Protección del Ambiente, Official Gazette, January 28, 1988.

⁷⁸ Through the Secretariat of the Environment, Natural Resources and Fishing (Secretaría de Medio Ambiental , Recursos Naturales y Pesca (SEMARNAP)) the Federal Government of Mexico has “sole jurisdiction over acts that include hazardous waste, and procedures for the protection and control of acts that can cause environmental damage or serious emergencies to the environment. The Secretariat's main activities are to make environmental policy and enforce it; assist in urban planning; develop rules and technical standards for the environment; grant (or deny) license, authorizations and permits; decide on environmental impact studies; and grant opinions on and assist the states with their environmental programs. This Secretariat enforces the law, regulations, standards, rulings, programs and limitations issued by it” (the information is taken from <http://www.mexicolaw.com/LawInfo08.htm>).

biotechnology, the General Act requires authorization of prior consent of the landowner where the resource is sought and sharing of benefits arising from the use of the resources with the landowner⁷⁹.

Moreover, it has been observed that the governments of a number of countries involved in projects of the ICBG (Peru, Mexico, Chile, etc) have used principles of the ICBG projects to develop national policies on access to genetic resources and associated TK and benefit sharing⁸⁰. For instance, Peruvian Law No. 27811 “Introducing protection regime for the collective knowledge of indigenous peoples derived from biological resources”⁸¹ requires the concluding of a license agreement in the event of access to TK of indigenous peoples derived from biological resources for the purposes of commercial or industrial use. The terms of the agreement must ensure PIC and equitable benefit sharing⁸². Another

⁷⁹ Rosenthal, *supra* note 60, at 380.

⁸⁰ McManis, *supra* note 58.

⁸¹ See Official Journal ‘El Peruano’, August 10, 2002

⁸² The law sets the following minimum of clauses:

- (1) Identification of the parties;
- (2) A description of TK to which the contract relates;
- (3) A statement of the remuneration (monetary or equivalent payment) that the indigenous peoples shall receive for the use of their collective knowledge; and a percentage of not less than five per cent of the value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge;
- (4) The provision of sufficient information on the purposes, risks and implications of the said activity, including any uses of the collective knowledge, and its value, where applicable;
- (5) The obligation on the licensee to inform the licensor periodically, in general terms, of progress

example of ICBG-derived national policy development was the passing of two legislative initiatives in Mexican Federal Congress after the termination of Maya-ICBG: the first one was proposed by the Federal Representative of the Institutional Revolutionary Party and the other one was proposed by the Federal Senator from the National Action Party. These two initiatives proposed a comprehensive regulatory framework to regulate access to genetic resources and ABS⁸³.

The collaboration scheme in ICBG projects is usually complicated. If one only considers recipients, these agreements already include such a complexity of elements as the one-contract model, the contract wheel, the dual-contract model, the wheel triangle model, sometimes MTAs, know-how licenses and other contractual arrangements which in turn consist of such clauses as research and benefit-sharing terms, intellectual

in the research on and industrialization and marketing of the goods developed from the collective knowledge to which the license relates; and

(f) The obligation on the licensee to contribute to the improvement of the ability of the indigenous peoples to make use of the collective knowledge relating to its biological resources.

The license agreement should be in writing, in the native language and in Spanish, for a renewable period of not less than one year or more than three years. The contracts must be registered by The National Institute for the Defense of Competition and Intellectual Property (INDECOPI). If contracts fail to conform with the provisions of the law they will not be registered. The Peruvian law states that the licensing of the use of the collective knowledge of an indigenous people shall not prevent future generations of the given indigenous community or other indigenous communities from using or licensing the same knowledge. Sub-licensing shall be allowed only with the express permission of the representative organization of the indigenous peoples that granted the license.

⁸³ Carrizosa S., Brush S.B., *et al*, "Assessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity", 54 IUCN *Environmental Policy and Law Paper* (2004) 144-146.

property rights, material transfer, confidentiality, etc⁸⁴. The aim of this section is to examine and analyze how TK holders' rights and TK itself are covered in ICBG models.

Since its first project in 1993⁸⁵ ICBG has built up and developed various models of contractual arrangements. Their common features are the following:

- **aim:** discovery of new drugs, economic development of indigenous communities, biodiversity conservation and sustainable economic growth;
- **general structure and form of agreement:** PIC and ABS agreements between bio-recipients, bio-suppliers and TK-holders;
- **negotiation process:** informed consent; disclosure of potential use of TK – first in an informal way and then formally in the project's documents and related materials; consensus building between indigenous communities, governmental organizations and nongovernmental organizations; independent legal consulting to all members of the contractual scheme;
- **parties to a contract:** unprecedented involvement of local communities or their representatives as a party to the agreement;
- **basic requirements for all ICBG agreements:** addressing of IP rights issues, prior-informed consent and benefit sharing;
- **the recipients of the benefits:** TK-suppliers - these may include individuals and communities, and they will always be compensated,

⁸⁴ Soejarto, *supra* note 48.

⁸⁵ *Id.*

regardless of whether or not the bioprospecting process is successful; communities receive both short- and long-term benefits for collaborating in the research process⁸⁶.

PIC is the most crucial part in all ICBG projects. The main distinguishing characteristics of ICBG PIC are:

- the recognition of communal ownership of TK
- the recognition of the possibility of harm to community interests

PIC has become an important instrument for raising awareness within communities regarding potential global values of their knowledge as well as the importance of biodiversity and the need to conserve it. As a result, ICBG strongly recommends that PIC be obtained at the “community” level prior to seeking it from individuals.

The ICBG Program provides a number of valuable examples of the private arrangement of collaborations between local communities (TK holders) and members of the global market, where academic researchers play a mediating role⁸⁷. Due to high public attention of the program and the timing of its activities and development relative to that of the U.N. Convention on Biological Diversity (CBD),⁸⁸ the ICBG Program offers a number of useful working models for national and international policies related to biodiversity conservation and development, TK transfer, intellectual property, PIC and benefit-sharing⁸⁹.

⁸⁶ *Id.*

⁸⁷ McManis, *supra* note 58.

⁸⁸ The full text of the Convention is available at CBD web site <http://www.cbd.int/> [last accessed December 2011].

⁸⁹ JOHN E. FOGARTY INTERNATIONAL CENTER

The contractual agreements signed by biodiversity prospectors and suppliers are all confidential⁹⁰. Thus ICBG agreements are not disclosed to the public; nevertheless the main clauses and general content of some ICBG projects are open to the public and described in different papers.⁹¹

Below is an overview of three of the leading ICBG projects.

2. The Peru-ICBG

The Peru-ICBG program (1994-1999)⁹² was the earliest ICBG program, in which traditional healing knowledge of the Aguaruna people was used in tropical plant research to develop new therapeutic methods against infections and chronic diseases. Along with new drug discovery, the aims of the project also included biodiversity conservation and community development. The scheme of the collaboration can be depicted as a triangle, (see **figure 4**). The research institutions were represented by Washington University (U.S.) and two Peruvian Universities. The industrial partner was Searle-Monsanto Company (U.S.)⁹³. The

<http://www.fic.nih.gov/> [last accessed December 2011].

⁹⁰ Tilford D.S., “Saving the Blueprints: the International Legal Regime for Plant Resources”, 30 *Case Western Reserve Journal of International Law* 373 (1998).

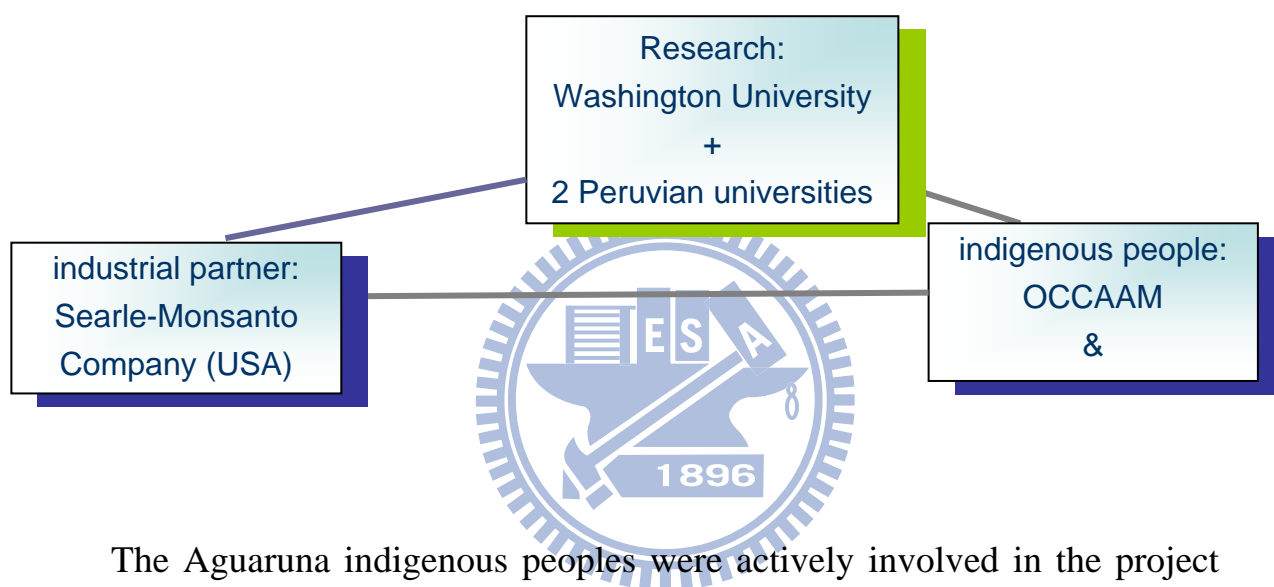
⁹¹ Rosenthal J., “Drug Discovery, Economic Development and Conservation: The International Cooperative Biodiversity Groups”, published as a special Supplement to 37 *Pharmaceutical Biology* 5 (Supplement 1999); McManis C, *Biodiversity & the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (Earthscan: 2007); Soejarto D.D., et al, “The UIC ICBG (University of Illinois at Chicago International Cooperative Biodiversity Group) Memorandum of Agreement: A Model of Benefit Sharing Arrangement in Natural Products Drug Discovery and Development” 67 *J.Nat. Prod.* 294-299 (2004).

⁹² Rosenthal, *supra* note 60, at 377.

⁹³ *Id.*, at 377.

indigenous people in this project, at the beginning, were represented by a small-clan Aguaruna organization called OCCAAM, and later, by another NGO called CONAP⁹⁴. Representing 55 communities, the indigenous NGO was self-organized. By the time the project started, the Aguaruna peoples already had their own collective decision-making mechanism.

Figure 4. The scheme of the collaboration in the Peru-ICBG program (1994-1999)



The Aguaruna indigenous peoples were actively involved in the project and participated productively in the whole PIC negotiation process. It was advised that all parties should have competent and independent legal counsel to present their interests in the negotiation process. The Aguaruna peoples had their own legal counsel and also an additional one from the Peruvian Society of Environmental Law (SPDA).

Another feature of this collaboration project was that there existed no non-aboriginal mediatorial NGO during negotiations between the bioprospectors and the Aguaruna organizational representatives. Such direct collaboration between bioprospectors and indigenous communities

⁹⁴ *Id.*, at 377-78.

is not usual in bioprospecting transactions and has its drawbacks. It can lead to the obvious case of an imbalance in bargaining power. Nevertheless, due to professional legal consultation, the Aguarunas managed to obtain several concessions from the bioprospectors, such as a prohibition on developing pesticides and GMOs. Monsanto also agreed on joint inventorship of patents, etc⁹⁵. Thus, according to the agreement, should the extraction and screening process result in any patents involving original TK, the Aguarunas in such patents would be recognized as inventors or at least as contributors to the inventions⁹⁶.

The legal arrangement for the ICBG-Peru project consisted of a set of agreements.⁹⁷ The basic agreement was a Biological Collecting Agreement, which described the parties to the project, terms of the bioprospecting and fees to be paid to the Aguaruna organizations by the industrial partner⁹⁸. A License Option and a License Option Amendment Agreement established the basic foundation of the collaboration between Washington University and Searle-Monsanto Company; it specified the amount and the terms of the royalties for the pharmaceutical products⁹⁹. Two more subsidiary agreements set the legal framework of the interactions between Washington University and the two Peruvian universities.

⁹⁵ *Id.*, at 380.

⁹⁶ McManis, *supra* note 58.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

In the ICBG-Peru program, TK was valued separately from material and genetic resources (plants and their chemical constituents) and was transferred under a know-how license model – The Know-How License Agreement¹⁰⁰. It was revolutionary and novel at the time¹⁰¹. Such a contractual approach confirmed the ownership that the indigenous communities had over their TK and allowed them to negotiate the terms of the transfer of this TK. This method made it possible for non-patentable information to be protected contractually. The indigenous knowledge (“know-how” according to contractual arrangement) was a disclosed subject in PIC and was retained in confidence against third parties¹⁰². The Agreement entailed that the medicinal TK of the Aguaruna people was considered valuable know-how and prescribed an annual TK transfer license fee and milestone payments to be paid by industrial partners to the Aguaruna groups.¹⁰³

According to the agreement, the royalty payments were made “based on a sliding scale, ranging from 1% - 2% of the net sales of a licensed product”¹⁰⁴. An industrial partner, Monsanto, paid 1% only if the following conditions were met: “the licensed product incorporates a plant extract, isolated or synthetic natural product or analog or isomer thereof present in such plant extract, and the product is sold for the same use as the historical use by the indigenous peoples who use the plant from

¹⁰⁰ *Id.*

¹⁰¹ Rosenthal, *supra* note 60, at 379.

¹⁰² McManis, *supra* note 58..

¹⁰³ *Id.*

¹⁰⁴ Asebey & Kempenaar, *supra* note 63.

which ... the extract was obtained”¹⁰⁵. The agreement stipulated that about half of the royalty payment (0.2%-1%) should first be used to reimburse the costs of the research and development conducted by the individual ICBG member institutions.¹⁰⁶ If the indigenous information regarding a biological compound was in the public domain already or could be known to the industrial partner, the TK holders might not receive any royalties¹⁰⁷.

The indigenous community’s representatives also tried to insert a “grant back” provision into the agreement: a royalty free license to the market-developed products in the country of TK origin. But they did not succeed in negotiating this term.

The ICBG-Peru project had several successful attributes. First of all, the rights and interests of the indigenous peoples were adequately represented. Secondly, the indigenous communities possessed a pre-existing collective decision-making process. Thirdly, there was quick and efficient cooperation among parties of the project. Monsanto tried its best to obtain PIC not only at the national level from the Peruvian government, but also from the indigenous peoples directly. The Aguaruna peoples obtained very strong legal support. Another key point that made the project successful was the involvement of the Peruvian and the U.S.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

government agencies that provided advice and reference points for the existing legislation¹⁰⁸.

The ICBG-Peru project nonetheless had its drawbacks. Though a large number of communities were involved, still some were left behind. PIC, licensing and other agreements were separated in time and place, and some of them did not cover all the stakeholders¹⁰⁹.

3. The Maya-ICBG

The Maya-ICBG (1998-2001)¹¹⁰ project was set to be implemented in the Mayan Region of the Highlands of Chiapas, Mexico¹¹¹.

Though the Maya-ICBG project was undertaken much later than the Peruvian one, it was less successful and was terminated early¹¹². The major goals of the project were discovery a drug from the plants and macrofungi widely used by the Highland Maya¹¹³, development of natural products, such as phytomedicines, and development of agroecological programs¹¹⁴. The members of the Maya-ICBG partnership were: the University of Georgia (UGA), El Colegio de La Frontera Sur (ECOSUR) – a local institution, Molecular Nature Ltd. (MNL) - a small natural products pharmaceutical and botanical company located in the U.K., and the PROMAYA non-profit organization, which represented the Highland

¹⁰⁸ Rosenthal, *supra* note 60, at 378.

¹⁰⁹ *Id.*, at 378-380.

¹¹⁰ *Id.*, at 380.

¹¹¹ Bastida-Munoz &Patrick, *supra* note 3.

¹¹² Rosenthal, *supra* note 60, at 385.

¹¹³ *Id.*, at 381.

¹¹⁴ Carrizosa, et al , *supra* note 83, at 140.

Maya¹¹⁵. Before the establishment of PROMAYA, the Maya had no organization to represent it. An associated trust fund, Chiapas' Highlands Fund¹¹⁶, was established to distribute any financial benefits from the project. PROMAYA was responsible for receiving the benefits and delivering them to the Highland Maya. The partnership was constructed in such a way that in case of surprising discovery rates (whether or not a commercially successful drug was developed) PROMAYA was entitled to a reasonable income¹¹⁷. And once the commercialization (filing for IP protection and negotiation of license agreement) was proven successful, according to the agreement, all the intellectual property would be co-owned and net revenue would be shared equally between ECOSUR, UGA, MNL, and Chiapas Fund; thus, Chiapas' Highlands Fund (and therefore Maya communities, regardless of their involvement in the project¹¹⁸) would receive 25% of net revenue from the drug IP license¹¹⁹.

A fairly integrated and sophisticated contractual arrangement was established, consisting of three main agreements: 1) the general Agreement on Benefit Sharing and Protection of IP, which described objectives and responsibilities of the scientific partners, including benefit-sharing among collaborating parties and recognized sovereign rights of the Mexican government over the genetic resources in compliance with CBD; 2) the Biological Material Transfer Agreement

¹¹⁵ Rosenthal, *supra* note 60, at 381.

¹¹⁶ Carrizosa, et al, *supra* note 83, at 141.

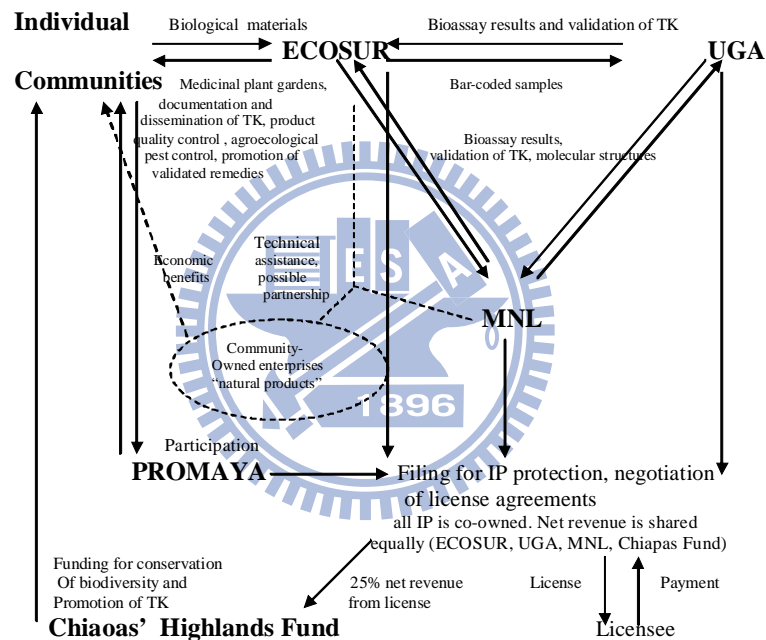
¹¹⁷ Rosenthal, *supra* note 60, at 384.

¹¹⁸ Sundaram S., "Battling Bills, Beans&Biopiracy", 15 *Albany Law Journal of Science and Technology* 545 (2005).

¹¹⁹ Carrizosa, et al, *supra* note 83, at 141.

provided the terms under which ECOSUR would transfer samples to UGA and MNL; 3) the Joint Ownership and Commercialization Agreement outlined the materials and derivatives that could be commercialized¹²⁰. Schematically, the Agreement could be modelled as follows:

Figure 5. The scheme of the collaboration in the Maya-ICBG (1998-2001)



Source: Santiago Carrizosa, Stephen B. Brush, Brian D. Wright, and Patrick E. McGuire, "Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity", 54 IUCN Environmental Policy and Law Paper (2004), p.141, available at <http://www.grcp.ucdavis.edu/publications/docABSPacRim/ABSPacRimwww.pdf>.

One of the most essential innovations of the Maya-ICBG contractual arrangement was that PROMAYA was a party to the Joint Ownership and

¹²⁰ Rosenthal, *supra* note 60, at 384.

Commercialization agreement that provided Maya participants with a right of joint ownership over patents, the right to prohibit publication or patent application if the activities harmed the communities, and a voice in any licence agreement under the Maya-ICBG partnership (including the right of veto)¹²¹. The Maya-ICBG project provided the most comprehensive benefit-sharing provisions, including technology transfer and dissemination of “scientifically-validated” traditional knowledge. These benefits were divided into short-term, middle-term and long-term benefits¹²².

Negotiation and contractual provisions were translated into native Mayan languages. The PIC from indigenous communities involved different forms of communication, including meetings with communities, leaflets in Mayan languages, radio broadcasts, and even a play¹²³. However due to some political and cultural reasons, Maya-ICBG received huge criticism from academics, NGOs and the mass media¹²⁴, and the project was terminated in 2001¹²⁵.

The contractual agreement in the Maya-ICBG is considered to be more integrated and sophisticated than that of the ICBG-Peru. The Maya-ICBG had a robust and careful design, but unlike the ICBG-Peru project, the

¹²¹ Carrizosa, et al, *supra* note 83 at 143.

¹²² *Id.*, at 141.

¹²³ *Id.*, at 142.

¹²⁴ Ni Kuei-Jung, “ Legal Aspects of Prior Informed Consent on Access to Genetic Resources: an Analysis of Global Lawmaking and Local Implementation Toward an Optimal Normative Construction”, 42 *Vanderbilt Journal of Transnational Law* 227 (2009).

¹²⁵ *Id.*

communities involved in the Maya-ICBG were not adequately represented and coordinated. There were many conflicts and disputes between them. In addition, the ethnobotanical TK was not properly organized.

4. The UIC-Vietnam-Laos ICBG

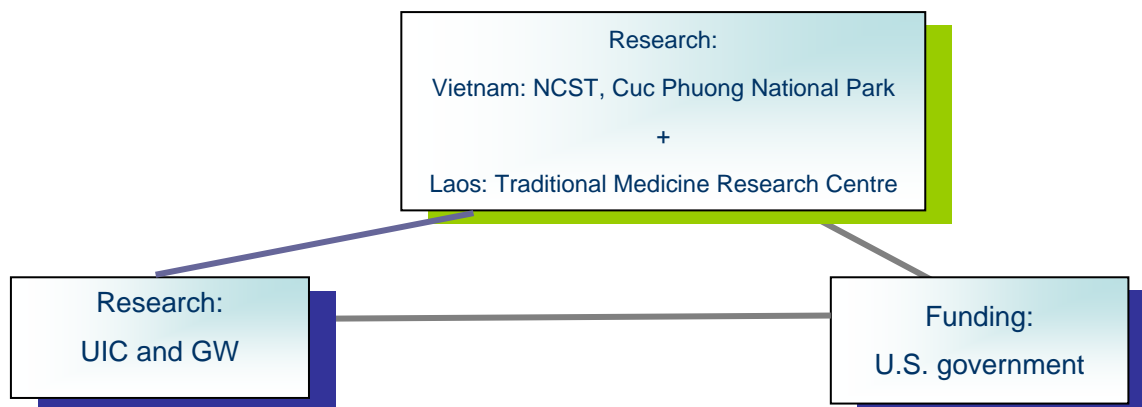
The ICBG UIC –Vietnam- Laos (1998-2003)¹²⁶ is a good example of collaboration between pharmaceutical corporations (industrial partner), research institutions of biotechnology-rich countries, and research institutions of biodiversity-rich countries. This collaboration took the form of a consortium and consisted of three main partners (see **fig.6**). The research part was represented on one side by University of Illinois at Chicago (UIC), U.S. and Glasgow Welcome Research and Development Ltd (GW) and on the other side by The Vietnam National Centre for Science and Technology (NCST) based in Hanoi, Cuc Phuong National Park, Vietnam and the Traditional Medicine Research Centre, Laos¹²⁷. The funding came from the U.S. government, which provided the UIC-based Vietnam-Laos ICBG project with a grant¹²⁸.

¹²⁶ Soejarto D.D., et al, “The UIC ICBG (University of Illinois at Chicago International Cooperative Biodiversity Group) Memorandum of Agreement: A Model of Benefit Sharing Arrangement in Natural Products Drug Discovery and Development”, 67 J.Nat. Prod. 294-299 (2004).

¹²⁷ *Id.*

¹²⁸ Grant 1-U01-TW-01015-01 (1998-2003).

Figure 6. The scheme of the collaboration in the ICBG UIC –Vietnam-
Laos (1998-2003)



The main goals of the consortium were¹²⁹:

- the discovery of biopharmaceuticals in the plants of Vietnam and Laos, with the subsequent development of drugs to treat cancer, AIDS, malaria, tuberculosis, pain, and diseases that affect the central nervous system
- creating a biodiversity inventory and conserving biodiversity, with a specific focus on plants of Cuc Phuong National Park and medicinal plants of Laos
- aiding economic development in cooperating communities
- capacity building among the collaborating institutions in the host countries.

The government of Vietnam and Laos were the owners of the genetic material and derivatives thereof¹³⁰. The UIC-Vietnam-Laos ICBG is an

¹²⁹ Soejarto et al, *supra* note 126.

¹³⁰ *Id.*

example of a bioprospecting collaboration scheme where neither indigenous peoples nor their representatives are parties to the conglomeration. Nevertheless the indigenous peoples are mentioned in the preamble of the Memorandum of Agreement¹³¹ (MOA) signed by all parties, in the context of purposes and benefit-sharing. The UIC-Vietnam-Laos ICBG main agreement also contains PIC stating that ICBG bioprospectors in Vietnam “*will seek the informed consent of individuals and/or communities for the recording and use of data on the medicinal and other uses of the plants in the Cuc Phuong National Park, for the intended study as described in the ICBG proposal*”¹³², and in Laos “*will seek the prior informed consent of individuals and/or the communities for the recording and use of data on the medicinal and other uses of plants of Laos, for the intended study as described in the ICBG proposal.*”¹³³

The reason for allowing the direct involvement of government in the project might have been more for political reasons than for risk reduction or consulting, as in the other ICBG projects. In addition, there was no industrial partner for the results’ commercialization. The property rights belong to the Vietnam and Laos governments.

As for royalty distribution, the UIC-Vietnam-Laos ICBG agreement stipulates that the first 50% goes to the collaborating institutions, inventors, and UIC administration, while the other 50% is to flow back

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

to communities in the country of origin of the genetic material that has contributed to the commercialization of the products; this flow back is accomplished through a trust fund¹³⁴.

The UIC-Vietnam-Laos ICBG is an alternative model of bioprospecting where there is no direct participation of indigenous communities.

5. Main findings: advantages and disadvantages of contractual arrangements

A contract is a very flexible instrument of TK protection¹³⁵. Thus a TK license agreement can combine licensing, PIC, ABS and Non-disclosure agreements into one integrated model. The advantages of such comprehensive contractual arrangements are convenience, better time management and the cutting of transaction costs. There are no set rules for terms and conditions. A wide range of different options for the contractual clauses are permissible. Contracts seem to be a highly transparent and structured system of TK protection. Contractual agreements offer a practical and flexible tool to allow participating parties to optimally structure a given agreement for access and transfer of TK in compliance with requirements of appropriate access and equitable benefit-sharing.

TK license contractual agreements are not a panacea and cannot alone adequately protect indigenous communities' interests¹³⁶. The joint

¹³⁴ *Id.*

¹³⁵ Pettit M., Jr., "Freedom of Contract, and the 'Rise and Fall'", 79 *Boston University Law Review* .263 (April 1999).

¹³⁶ Balick, *supra* note 12, at 295.

ownership of TK and weak positions of indigenous communities in the international arena create difficulties for these communities in that they become weak parties to these contracts and experience difficulties in ensuring that the contracts are enforced in their favor.

TK is usually undocumented, without a date of invention. These properties create difficulties for the defining of the object of the contract and TK commercial evaluation¹³⁷.

A central problem with the use of contracts to protect TK is the unequal bargaining power of the parties¹³⁸. Indigenous communities have little experience in negotiating or defending TK access and licensing agreements, and as a result, they often lose such bargains. Though growing awareness within indigenous communities and the involvement of local and international NGOs in the negotiation and contracting process has improved the situation, the assistance and training of TK holders is still an issue of priority. Problems of implementation and enforcement constitute inherent weaknesses of these contracts.

D. Solutions for unequal bargaining powers in the private contracting schemes

1. Doctrine of contracts: understanding and solutions

There exist some limitations to a contract's freedom, recognized in the classical theory: involving illegal acts, unlawful means, involving minors

¹³⁷Bodeker G., "Traditional Knowledge, Intellectual Property Rights & Benefit Sharing", 11 *Cardozo Journal of International and Comparative Law* 385 (2003).

¹³⁸ *Id.*

or mentally incapacitates, etc. No such factors as “the perceived moral or social value of a contracted-for activities, the alternatives available to the contracting parties (e.g. one of the party is a monopolist), the intelligence, sophistication, and independence of the contracting parties... and, perhaps most importantly, the basic fairness of contractual terms”¹³⁹ under the classical notion of freedom of contract should matter, but the courts and legislators usually consider them.

Freedom of contract can be limited by the courts in three main ways:

- through the procedures for making contracts;
- regulating the content of contracts (implying/prohibiting some specific terms). For example when international law describes some situations in which one of the parties is liable, but only if otherwise it is not stipulated in a contract (so called “default terms” or “implied terms” which can be found in the law of sale, lease or whatever type of contract even in the laws regulating TK transfer)¹⁴⁰;
- imposing the entire contract.

Doctrines of mistake, fraud, duress, offer and acceptance are applied while analyzing the formation of a contract. The obligations of the contracting parties are determined by using general canons of interpretation.

¹³⁹ *Id.* at 298.

¹⁴⁰ *Id.* at 7.

Applying the theory described above to the contracts of TK transfer it can be assumed that indigenous people will be that “weaker party” to a contract with a lack of understanding, choice, power, etc. And due to the dominance of the classical contract theory, with its notion of contract freedom, the contracts are tended to be enforced in most of the cases. Nevertheless, as it has been mentioned above the courts understand that “it is wrong to take advantage of another’s vulnerability”¹⁴¹, for example, misappropriation of indigenous people’s knowledge, and use the doctrine of limitation of contract’s freedom. The common explanation for the limitations of contracts here is that indigenous people and companies who enter such agreements can harm the heritage and nature (basic notions of fairness and basic social values).

2. Solutions derived from ICBG case –study

2.1 The involvement of government

One of the solution to enhance bargaining power of TK holders is the assistance of government in the negotiation, drafting, implementation, and enforcement of contracts.

The government may organize different training programs to educate indigenous communities on how to protect TK and derive benefits from its utilization. It is important to encourage TK holders to develop broader participation with bioprospectors in order to build a trustworthy and reliable form of collaboration.

¹⁴¹ *Id.* at 8.

If there is no direct participation of the indigenous communities in bioprospecting agreement, the role of the government becomes crucial¹⁴². Vietnam-Laos-ICBG is a good example of dissemination of royalties derived from TK implementation to local communities with the help of the government¹⁴³. Even if indigenous communities have their own strong representation in collaboration with industries and other partners, the involvement of the government can also be helpful as either a guarantor or advisor (i.e. Peru-ICBG).

2.2 Legal support of indigenous peoples

In developed countries, to have access to independent private counsel is quite common (New Zealand, North America), but it is still not very common in the developing world.¹⁴⁴

As shown from the ICBG experiences, different groups of indigenous peoples have different levels of legal support. For instance, the communities in Peru were already “matured” enough and had their own legal counsel and also an additional one from the Peruvian Society of Environmental Law. Professional legal consultation helped the Aguarunas to obtain several concessions from the bioprospectors, such as a prohibition on developing pesticides and GMOs, and also a joint inventorship of patents.

2.3 Property rights in TK

¹⁴² Dutfield, *supra* note 14.

¹⁴³ Soejarto, at al, *supra* note 48.

¹⁴⁴ Rosenthal, *supra* note 60, at 379.

The ownership ensures that indigenous peoples can engage in the agreements with the state and third parties as active stakeholders rather than as passive beneficiaries.

According to the ICBG policy if TK is involved in drug discovery and the TK provider cannot be recognized as an inventor, the TK should be treated as know-how and the provider should be compensated for it. This policy is reflected in the ICBG-Peru program, wherein traditional knowledge was valued separately from material and genetic resources and was transferred under a know-how license agreement with annual TK transfer license fee and milestone payments to be paid by industrial partners. Such an approach confirms the ownership that the indigenous communities have over their TK and allows them to negotiate the terms of the transfer of this TK. Treating TK as know-how considerably enhanced the bargaining power of the Peruvian local communities.

The recognition of the existing intellectual property rights¹⁴⁵ of indigenous people over traditional knowledge allows TK holders to maintain control over TK and constitutes an affirmative positive protection that has no problems with international recognition. While confidential information would provide indigenous people with infinite coverage, sharing the knowledge within the entire community may mean that TK is already in the

¹⁴⁵ Some biodiversity rich countries such as Panama and Peru established special forms of property for traditional knowledge (see Panamanian Law No. 20 on “the Special IP Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and Their Traditional Knowledge” and Peruvian Law No. 27811 “Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources”), but this *sui-generis* system is not recognized world-wide.

public domain and therefore may lack “quality of confidence”¹⁴⁶. These and other concerns regarding applying trade secrecy for TK protection are described and analyzed in the following Part III.

E. Conclusion

Some general conclusions can be made following the analysis of these three different projects¹⁴⁷. Each project under ICBG is a kind of “bridge” or a collaborating platform that brings together interested parties in the formulation of an agreement and provides a mechanism for negotiations. The ICBG Program ensures a relatively integrated and successful international licensing scheme of collaboration between indigenous communities, research institutions and private entities (U.S., international or multinational)¹⁴⁸, which provides development of creative potential

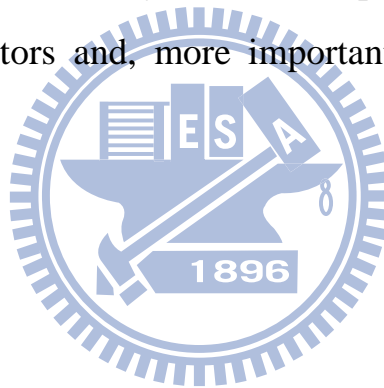
¹⁴⁶ Mazonde I., Thomas R., «Indigenous Knowledge systems and intellectual property in the twenty-first century: perspectives from Southern Africa», 19 *Syracuse Society and Technology Law Report* 92 (2008).

¹⁴⁷ McManis C.R., “Intellectual Property, Genetic Resources and Traditional Knowledge Protection: thinking Globally, Acting Locally”, 11 *Cardozo Journal of International and Comparative Law* 547 (2003); Rosenthal J., “Politics, Culture and Governance in the Development of Prior Informed Consent and Negotiated Agreements with Indigenous Communities”, in *BIODIVERSITY & THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE* 373-393 (Charles McManis ed., 2007); Asebey E.J., Kempenaar J.D., “Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention”, 28 *Vanderbilt Journal of Transnational Law* 703 (1995); Soejarto D.D., et al, “The UIC ICBG (University of Illinois at Chicago International Cooperative Biodiversity Group) Memorandum of Agreement: A Model of Benefit Sharing Arrangement in Natural Products Drug Discovery and Development”, 67 *J.Nat. Prod.* 294-299 (2004), Carrizosa S., Brush S.B., Brian D. et al “Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity”, 54 *IUCN Environmental Policy and Law Paper* (2004).

¹⁴⁸ According to the ICBG Eligibility statement (See FIC web site at <http://www.fic.nih.gov/>) “...non-U.S. entities (foreign organizations and regional organizations) are eligible to participate as

solutions for biopiracy and efficient exploitation and sustainable use of biological resources and associated TK¹⁴⁹.

ICBG projects are characterized by high involvement of TK holders or their legal representatives in contractual agreements as a rightful party. Prior informed consent and associated measures are a mandatory part of all ICBG projects. On the other hand, the TK holders and their representatives may encounter some limitations such as weakness of bargaining power and difficulty of enforcement. Although certain shortcomings remain, the ICBGs' contract models are a good example of how contractual agreements may be able to properly protect both the interests of bioprospectors and, more importantly, the interests of TK holders as well¹⁵⁰.



members of a Group but are not eligible to be the principal applicant organization”. The multinational industrial partners in ICBGs possess huge technological potential for bioprospecting (their biological resources screening programs can test up to 10,000 samples per week). Therefore it is encouraged to involve more pharmaceuticals and biotech companies to participate in preliminary screening of the obtained biological material (Asebey E.J., Kempenaar J.D., “Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention”, 28 *Vanderbilt Journal of Transnational Law* 703 (1995)).

¹⁴⁹ Sundaram, *supra* note 118.

¹⁵⁰ McClelland L., “Bioprospecting: Market-based Solutions to Biopiracy”, 8 *UCLA Journal of Law and Technology*. Notes 8 (2004).

III. Assessment of treating TK as trade secret (know-how) to enhance bargaining power of indigenous peoples in bioprospecting transactions

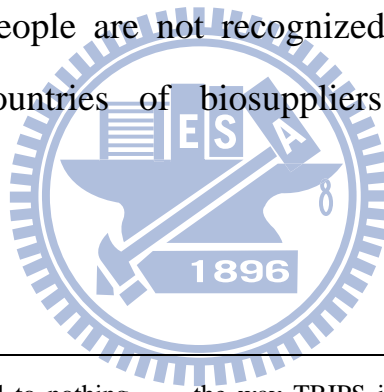
1. Introduction

The existing international legislature in respect to the genetic resources and associated traditional knowledge is already rich and diverse: The Convention on Biological Diversity, the CBD Bonn Guidelines on Access to Genetic Resources and Benefit Sharing, World Intellectual Property Organization and its working groups' initiatives, different international indigenous conventions, declarations and other international institutions. Much has been done on the way of protection of indigenous communities and their rights since this issue for the first time was addressed in Earth Summit in Rio de Janeiro at 1992. But little has been done to safeguard indigenous intellectual property interests. All the protective measures merely boil down to liability protection¹⁵¹: prior informed consent, access and benefit sharing. And what is more important they are not legally binding for the member-states, but rather constitute a soft law: advice, recommendation, guideline. Such hard law as the Agreement on Trade-Related Aspects of Intellectual Property Rights doesn't recognize property rights in TK¹⁵².

¹⁵¹ Arezzo E., "Struggling Around the "Natural" Divide: the Protection of Tangible and Intangible Indigenous Property" (2007) 25:1 *Cardozo Arts and Entertainment Law Journal* 367.

¹⁵² "When goods and services are made possible by combining traditional knowledge with western science, the contributor of the western scientific thinking is entitled to patent protection — a recognition of his or her property interest in creations of the mind — under TRIPS, the contributor of

Whether there should be a property protection of TK – is a hot debatable issue among developed and developing countries. It is important that such recognition should be not only on national and regional levels, but internationally binding. Thus national laws of some countries with rich genetic resources and traditional knowledge such as Brazil, Panama or Peru have recognized indigenous communities’ intellectual property rights over TK and require bioprospectors to sign licensing TK contractual agreements, but such contracts are not widely practiced¹⁵³. As some experts explain, the problem is in the high transaction costs¹⁵⁴. But in my opinion, the problem is in property rights allocation. The property rights of indigenous people are not recognized world-wide: even it is recognized in the countries of biosuppliers, in the countries of bioprospectors it is not.



traditional knowledge is entitled to nothing... ..the way TRIPS is structured, it is difficult, if not impossible, for indigenous groups to claim any intellectual property rights over the unmediated products of their traditional knowledge... At its worst, TRIPS legitimizes the transfer of exclusive ownership and control of biological resources and traditional knowledge from indigenous innovators to western ones, with no recognition, reward or protection for the contributions of the indigenous innovators” (Bratspies R., “The New Discovery Doctrine: Some Thoughts on Property Rights and Traditional Knowledge” (2007) 31:2 *American Indian Law Review* 315).

¹⁵³ See the Brazilian Provisional Measure On Access to Genetic Resources and Traditional Knowledge No. 2.186-16, of August 23, 2001 (Provisional Measure, 2001); the Panamanian Law No. 20 of 26 June 2000, ‘On the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge’; and the Peruvian Law No. 27811 ‘Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources’, published on August 10, 2002, respectively.

¹⁵⁴ World Intellectual Property Organization (2001) *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge*, (WIPO/GRTKF/IC/2/5), p.5.

First efforts to apply IPRs tools to TK at the multilateral level were taken at the Doha Ministerial Conference of the WTO in 2001¹⁵⁵. Such “positive” protection as IPRs (for example, trade secrets)¹⁵⁶, are considered to be one of the feasible means to secure TK.

2. Legal and economic justifications

2.1 Rationales for protection of TK as intangible goods

Indigenous and local communities possess, use and preserve traditional knowledge from generation to generation. TK is a part of their life both physical and spiritual¹⁵⁷. The things, that are “bound up” with personhood and are not so easy to be exchanged and even evaluated are referred to personal property, and therefore need stronger protection such as “property rules” approach¹⁵⁸. For aboriginal communities TK is just that “personhood” property which consists not only of the inventions, technologies and creative works, it is the expression of the human soul in all its aspects, as well as the foundation for the economic, social and spiritual growth¹⁵⁹.

¹⁵⁵ World Trade Organization (2001) Ministerial Conference, Ministerial Declaration (WT/MIN(01)/DEC/1 20 November).

¹⁵⁶ Overwalle G., “Holder and User Perspectives in the Traditional Knowledge Debate: European View”, in C. McManis (ed.), *Biodiversity & the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (London: Earthscan, 2007), 355.

¹⁵⁷ Overwalle, *supra* note 156, at 359.

¹⁵⁸ Radin J., “Property and Personhood” (1982) 34 *Stanford Law Review* 957.

¹⁵⁹ Anaya J., *Indigenous Peoples in International Law*, 2d ed (New York: Oxford University Press, 2004)

The question is whether the communally owned TK can be personal at the same time. The western concepts of “individual”, “private”, “personal” right can’t fit the communally developed and preserved knowledge. Nevertheless the analogies can be drawn: though TK is not personified but belongs to many indigenous members, these members form a single organism and can be regarded as ‘one person’ the same as a legal person (for outsiders it is a single person, but inside it is formed of several/many individuals)¹⁶⁰. Besides, the word “personal” in Radin’s article¹⁶¹ means relation to personhood rather than that the owner is a single person. The term “private” can be explained in the same way: traditional knowledge is private to the community, likewise some individual innovation to an inventor. “Private” also means sacred, personal, which is undoubtedly true for the indigenous group.

Even for indigenous peoples it is not common to describe their knowledge in terms of property. They view themselves not as the owners but more as custodians that have a responsibility to respect, preserve and maintain traditional knowledge¹⁶². And it is not a drawback of indigenous society, but a difficult task of an international community to

¹⁶⁰ Carol Rose calls such property “limited common property” (LCP): the community resources are allowed to use for insiders, and are excluded from outsiders. The problem is that LCPs are usually invisible to outsiders from the West who assume property only as private forms of ownership (Rose C.M., “The Several Features of Property: Of Cyberspace and Folk Tales. Emission Trades and Ecosystems” (1998) 83 Minnesota Law Review 129).

¹⁶¹ Radin, *supra* note 158.

¹⁶² Overwalle, *supra* note 156, at 359.

rethink and to reconsider property rights that can be applied to the communities instead of states or individuals¹⁶³.

2.2 Using special property in TK

What problems may occur if indigenous peoples get property right control over TK? The control over resource related to personhood may harm the personhood¹⁶⁴. For instant, “crooked” members of an indigenous society may disclose and/or sell knowledge to non-community members without the community consent. Such actions can bring a lot of harm, disorder and even ruin the community. In order to prevent misuse of property ownership in TK by some indigenous members and its overcommodification, inalienability measures can be taken, such as intentionally disclosing information about traditional knowledge so that it may count as prior art and defeat any claim of IPR over TK.

Another “recipe” to prevent monopolization, unfair trade and use of TK is to negotiate multilateral licensing agreements rather than bilateral contracts between one corporation and one biosupplier¹⁶⁵.

Another argument, opposing IPRs in TK, is based on the notion that such strong property constraints may limit the free flow of TK from

¹⁶³ Bratspies R., “The New Discovery Doctrine: Some Thoughts on Property Rights and Traditional Knowledge” (2007) 31:2 *American Indian Law Review* 315

¹⁶⁴ Radin, *supra* note 158.

¹⁶⁵ Overwalle, *supra* note 156, at 362.

indigenous world to the modern society¹⁶⁶. When more and more exclusive rights are granted over each piece of traditional knowledge, neither indigenous communities nor even bioprospectors themselves will be able to use the traditional knowledge¹⁶⁷. Such phenomena in the property rights theory is called “the tragedy of anticommons”, and was introduced by Michael Heller¹⁶⁸. The anticommons problem would occur when many parties have been granted exclusive overlapping right over the same scarce resources, so that each of them faces high transaction costs to separate his share from the other’s shares. Such situation leads to underexploitation of the property. Under-utilization of TK may end up with huge loses not only for the pharmaceutical and biotechnology industries, but for the whole society, depriving it of new drugs, medicines, healing technologies, food, food additives, cosmetics etc.

Hansmann & Kraakman¹⁶⁹ propose the cost-benefit test to calculate the efficiency of introducing new property rights. Such test is more likely to have positive result for those rights that have high value to their users, moreover the demand in this rights will increase under the new property right regime. On the contrary, Hansmann & Kraakman states that if the created property right is of little value and is not frequently used, the high nonuser costs and system costs make the facilitation of new property

¹⁶⁶ Carvalho N., “From the Shaman’s Hut to the Patent Office: A Road Under Construction”, in C. McManis (ed), *Biodiversity & the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (London: Earthscan, 2007), 241.

¹⁶⁷ Arezzo, *supra* note 151.

¹⁶⁸ Heller, *supra* note 43..

¹⁶⁹ Hansmann, *supra* note 39.

rights unworthy. In Hansmann & Kraakman's approach the value and use of a right are crucial in making decision of creating new property rights. The direct users of TK related to genetic resources are biotech companies, and the information regarding the use of biological resources in drugs, food, cosmetic development is extremely valuable. And the consumers of biotech products (indirect users) only increase the value and demand in TK. Hereupon due to a high value of TK to its users – direct and indirect – the statement that property rights will deter bioprospectors from using TK will not necessarily be true. It could have happened so several decades ago when bioprospecting and interest to indigenous knowledge were not so huge and widespread.

The consideration that the intellectual property policy-makers should mind how creating property rights will influence the price of an ended products: medicines, drugs cosmetics. As soon as indigenous peoples have IPRs in TK, bioprospectors will have to sign licensing agreements with TK holders to get the useful information, which they used to get almost for free or for some symbolic compensation. The social costs will increase. As for the benefits, creating IPRs in TK will not only bring indigenous communities substantial profits from IP licensing, but also will induce indigenous peoples more actively preserve, maintain and promote their useful and valuable knowledge and technology¹⁷⁰, opening new prospect and horizons for science and industry what constitutes benefits not only for the industrial corporation but for the whole society as well.

¹⁷⁰ Carvalho, *supra* note 166, at 245.

2.3 Using existing IP tools to protect TK

2.3.1 Pros and cons of using existing IP tools to protect TK

Another option is to use already existing IPRs: for example, patents, copyrights, unfair competition and trade secret, etc. At the same time some legal scholars¹⁷¹¹⁷² doubt that existing IP regimes are suitable for TK protection. Their main argument is that it is not easy to superimpose strictly developed intellectual property rights on the unspecified holistic traditional knowledge in general and genetic resources associated TK in particular.

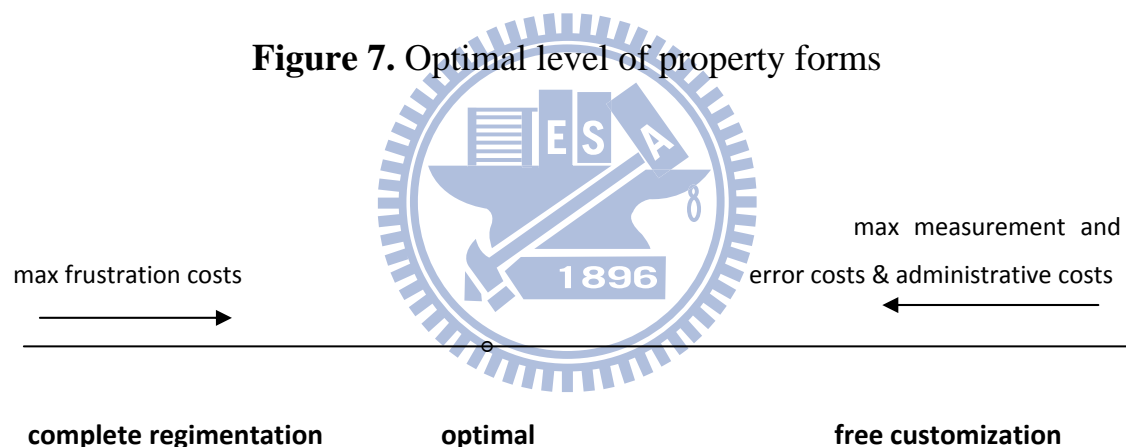
Resting upon the cost-benefit approach the main contra-argument of using existing IPRs instead of establishing, for example, *sui generis* system (special laws for protecting TK), is avoiding the high administrative and measurement costs of creating new property rights¹⁷³. Merrill&Smith give economic analysis of such legal principle as *numerus clauses* – a principle explicitly implied in civil-law jurisprudence and implicitly (but not with less extend) in common law systems, the main purpose of which is to prevent externalities resulting from creation of idiosyncratic property rights and lead the whole jurisprudence system to an optimal number of property forms. The spectrum of the approaches to the property rights according to Merrill&Smith is varied from very free “customization” to a “complete regimentation”. Complete regimentation

¹⁷¹ Dutfield, *supra* note 14.

¹⁷² Gervais D., *The TRIPS Agreement: Drafting History and Analysis*, 3d ed (London: Sweet & Maxwell, 2008).

¹⁷³ Smith H., Merrill T., “Optimal Standardization in the Law of Property: The Numerus Clausus Principle”, *Yale Law Journal*, 110 (2000).

(strictly fixed number of property forms) is a situation when frustration costs are at their highest, and the free customization (no limitations for new forms of property rights) – when measurement and error costs to third parties and administrative costs are at their highest. Considering social costs, Merrill&Smith point that none of these two extreme points lead to its minimization: “the number of forms of property is subject to tradeoff between measurement and error costs on the one hand and frustration costs on the other” and “the *numerus clausus* principle can be seen as a device that moves then system of property rights in the direction of the optimal level of standardization” (see **Fig. 7**).



Merrill&Smith don't argue that the particular number of property forms in some particular legal regime is optimal and doesn't need any improvement, though they argue that *numerus clausus* leads the property rights system to a more optimal state than it would be under either the complete regimentation or complete freedom of customization. Moreover economically justifying *numerus clausus* principle that watches over a

very closed property rights regime when “the chances of persuading a court to create a new type of property in any particular case are too remote to be taken seriously”¹⁷⁴, the authors also show how the given property regime with a fixed number of options can still leave the room for some deviations. Merrill&Smith compare property forms with building bricks, manipulating with which one can serve his particular goals of specific property rights arrangement and therefore overcome frustration costs. This opportunity of manipulation with “property-bricks” is called “the generative power of the system of property rights”¹⁷⁵.

Besides avoiding administrative, information and measurement costs of creating new IPRs, other benefits of using existing property regime are almost the same as in using new property forms: profits from patent licensing, stop huge loss from biopiracy, incentives for disclosing in patent applications unknown useful indigenous technological knowledge and therefore more profits for TK holders and users, and social benefits from new inventions. But not all forms of IPRs would be appropriate for TK. For instance, patent application, prosecution, maintenance, litigation are all very costly^{176,177}. Not all indigenous communities will be able to bear them¹⁷⁸. Potential patents in TK also may cause a lot of problems (constituting prior art and patent invalidity) to existing patents in

¹⁷⁴ Smith&Merrill, *supra* note 173.

¹⁷⁵ *Id.*

¹⁷⁶ Overwalle, *supra* note 156, at 362.

¹⁷⁷ Ramesh R., *India Protects Remedies from Foreign Patents*, online: The Hindu India's National Newspaper, available <http://www.hindu.com/2009/02/24/stories/2009022455911100.htm> [last accessed on July 2011].

¹⁷⁸ Overwalle, *supra* note 156, at 360.

biotechnology, that are based on traditional knowledge. Moreover, as we mentioned, above traditional knowledge in genetic resources *tel quel* doesn't strictly meet the requirements of patentability, in addition ambiguity in ownership and inventorship requires legal clarification, therefore some administrative costs will follow. Hence, other existing forms of IP, rather than patents, should be considered.

2.3.2 An assessment of using trade secrets to protect indigenous knowledge

The knowledge kept by indigenous communities and not revealed to the other communities or non-indigenous world may be protected as trade secrets under TRIPS Article 39.1¹⁷⁹. Unlike genetic resources, the rights over traditional knowledge belong to indigenous communities themselves¹⁸⁰. It means that indigenous peoples can sell or license their knowledge and get benefits separately from the government¹⁸¹. Confidential clauses together with the clauses ensuring fair benefit

¹⁷⁹ Torres P., "An Overview of International Trade Secret Protection from the International Trade and Investment Perspective" (2001), online: National Law Center for Inter-American Free Trade <<http://www.natlaw.com/pubs/spmxip14.htm>>[last accessed on July 2011].

¹⁸⁰ CBD as well as Bonn Guidelines call indigenous people "holders" of TK. Bonn Guidelines in General Provisions (Bonn Guidelines, 2002) clearly states that it doesn't assign any rights over genetic resources, and TK is not viewed separately from these resources in the Guidelines, but is associated with them. The Guidelines also refers to the legal pre-eminence of CBD. CBD Article 8j (CBD, article 8j, 1993) mentions the rights of indigenous and local communities, though it doesn't describe what are these rights. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in the "Revised Objectives and Principles" refers to the indigenous communities as TK holders (WIPO/GRTKF/IC/9/5, 2006). However, Mexico proposes to change the word "holder" to "owner", commenting that "the right in traditional knowledge already belongs to the owners of the rights and/or the communities, and the aim of the law will be to recognize such a right not to grant it" (WIPO/GRTKF/IC/11/5(b) Add., 2007, pp. 17-18).

¹⁸¹ Bates, *supra* note 46..

sharing based on mutual agreed terms between TK users and owners resulted in a contract may become a strong instrument for the protection of indigenous communities and their rights to ensure fairness of transactions between the parties. For instance, in the Peruvian ICBG project¹⁸² TK was valued separately from material and genetic resources (plants and their chemical constituents) and was transferred under Know-How License Agreement¹⁸³.

Any kind of IP protection needs some actions from a seeker of this protection. The costs of these actions differ depending on the form of IPRs. For example, as it was indicated above, it is difficult for an indigenous community to get patent or challenge a patent involving TK due to high costs of registering and litigation. It is always argued that for archaic indigenous communities it is especially problematic to go through all these “western-IP” formalities of the industrial world.

Although remedy is available in the laws of developed countries, such as the re-examination proceedings in the U.S., the financial, technical and legal costs for initiating such proceedings are exorbitantly high. As pointed out by India in one of its papers to the WTO, it would be more cost-effective to establish an internationally accepted solution to prevent biopiracy than to divert national resources to expensive judicial processes for the revocation of patents¹⁸⁴.

¹⁸² Rosenthal, *supra* note 60, at 377.

¹⁸³ McManis, *supra* note 58.

¹⁸⁴ Anuradha R.V., *Biopiracy and traditional knowledge*, online edition: The Hindu India's National Newspaper the special issue EARTHSCAPES <<http://www.hinduonnet.com/folio/fo0105/01050380.htm>>[last accessed on July 2011].

From this angle of view, trade secret seems to be different: there are no registration requirements as for other IPRs like patents, copyrights, trademarks. No special fees are to be paid for obtaining trade secrecy protection. Another advantage of trade secret is that, unlike patent law, there is no any requirement to a subject matter of protection, such as documentation, scientific in character, novelty, etc. It is essentially important for the holistic TK.

Nevertheless in order to be protected under trade secret law the TK should meet hree basic criteria¹⁸⁵:

- (1) to be secret, not generally known among persons within the circles that normally deal with the kind of information in question;
- (2) to have commercial value because it is secret; and
- (3) to be subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

The traditional knowledge that doesn't go outside community might meet the first criteria. Though being commons (with limited or open access to all community members)¹⁸⁶ inside the indigenous community, traditional knowledge by means of protective steps can be closed¹⁸⁷ to

¹⁸⁵ TRIPS, 1994, Section7, Article 39.

¹⁸⁶ Lee Ann Fennell contrasts “open-access resource that anyone can exploit” to “a limited access commons that is closed to all but its members” (Fennell L.A., “Commons, Anticommons, Semicommons”, in K. Ayotte, H.E. Smith (eds), *Research Handbook on the Economics of Property Law*. (Cheltenham: Edward Elgar, 2010).)

¹⁸⁷ Traditional knowledge can be “property on the outside” (Rose C., “The Several Features of Property: Of Cyberspace and Folk Tales. Emission Trades and Ecosystems” 83 *Minnesota Law Review* 129 (1998).)

the other community members, other communities and non-indigenous world¹⁸⁸¹⁸⁹ .

As indicated above, TK has a great socio-economic and commercial value. Traditional knowledge has the same scientific character as the “western” scientific knowledge, it can even be new and innovative: “tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields”¹⁹⁰. “Traditional” merely means the way it is preserved, but not something archaic¹⁹¹. It aids in the development of new products, especially medicinal ones very useful for modern world; identifies plants and animals with biologically active compounds (Arezzo, 2007). A substantial segment of the pharmaceutical industry is investigating TK of indigenous peoples to target the most promising plants and animals¹⁹². It also has socio-ecological value. Hence, it helps to avoid loss of biodiversity: includes the priceless information how to preserve and maintain biodiversity in sustainable way¹⁹³; plays important

¹⁸⁸ Overwalle, *supra* note 156, at 359.

¹⁸⁹ Dutfield, *supra* note 14, at 105.

¹⁹⁰ World Intellectual Property Organization (2001) *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge*, (WIPO/GRTKF/IC/2/5).

¹⁹¹ Dutfield, *supra* note 14, at 91-95.

¹⁹² Arezzo, *supra* note 151.

¹⁹³ CBD (1993), Article 8j «In-situ Conservation”.

role in food security¹⁹⁴.

The central among “the prerequisites to more formal legal protections”¹⁹⁵ under trade secret law is the actions taken by indigenous communities on keeping secrecy - self-help. Such actions can be undertaken on two different levels.

First, traditional communities have their internal “traditional” methods to preserve TK and to protect its leakage¹⁹⁶. For example, the healing methods are passed only among healers or shamans¹⁹⁷; or some punishment for disclosing TK to those, who are not eligible to know it. The question is: are these measures reasonable enough to protect TK from stealing?¹⁹⁸ It is important to note that not all indigenous knowledge is kept under high secrecy, only the most sacred one. Another reason of TK leakage could be a lack of general education and particular legal unawareness that leads to negligence in TK disclosure by community members¹⁹⁹. The most obvious solution is to train and educate indigenous communities how to protect TK from outside users and get benefits from its commercialization. Moreover it can happen that traditional knowledge belongs to a group of communities that live

¹⁹⁴ Salazar S., “The World of Biotechnology Patents”, in Bellman et al. (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (London: Earthscan, 2003), 126.

¹⁹⁵ Lichtman D., “How the Law Responds to Self-Help” (2004) U Chicago Law & Economics, Olin Working Paper No.232.

¹⁹⁶ Carvalho, *supra* note 166, at 246.

¹⁹⁷ Balick M., “Traditional Knowledge: Lessons from the Past, Lessons for the Future”, in C McManis (ed.), *Biodiversity & the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (London: Earthscan, 2007), 290.

¹⁹⁸ The trade secret law requires that measures should be reasonable (TRIPS, Article 39, 1994).

¹⁹⁹ Overwalle, *supra* note 156, at 361.

separately from each other. The solution here is a close cooperation between related communities. For example, Aguaruna people in Peru formed indigenous NGO representing 55 communities to deal with bioprospectors under Peru-ICBG program²⁰⁰.

Another level of self-help actions is when indigenous communities start using “western” methods of protection of their TK: creating special closed databases (Central and South American countries, India), the information in which is strictly protected; or/and signing a non-disclosure agreement (NDA) with TK users²⁰¹.

3. Conclusion

The international consensus over property rights in TK has not been found yet. This chapter has sought to suggest several argumentations for using either new forms of property rights specially tailored for TK or already existed IP tools. Although both approaches are economically justifiable, the existing IPRs are more possible to be applied due to avoiding administrative, information and measurement costs of creating new IPRs. Not all forms of IP are appropriate for indigenous communities. Hence, it is argued to apply trade secrecy to secure and transfer TK.

In respect to trade secret law, such arguable issues as whether traditional knowledge fits into the definition of intellectual property, whether it is scientific, new and novel can be simply avoided. In respect to self-help,

²⁰⁰ Rosenthal, *supra* note 60.

²⁰¹ Dutfield, *supra* note 14, at 106.

trade secret instrument of TK protection is more costly than, for example, patents²⁰².

When applied to knowledge belonging to a community, the community must make a reasonable effort to maintain the secrecy of the knowledge, otherwise protection is not applicable to the traditional knowledge.

Without recognition of intellectual property rights of indigenous communities over their traditional knowledge, which is resulted in the weak bargaining power of TK holders, all the contractual arrangements would be biased whereby indigenous communities in the best possible scenario are rewarded only for the biological resources and are not compensated for the intellectual resources they provide. There is still a long way for introducing property rights in TK recognized worldwide. Ultimately, it is in the policy-makers' hands to decide whether to extend property rights to TK, or leave vast, fertile prairies of this valuable asset as common heritage easily reachable for biotech companies and research institutions from other countries to profit from its utilization.

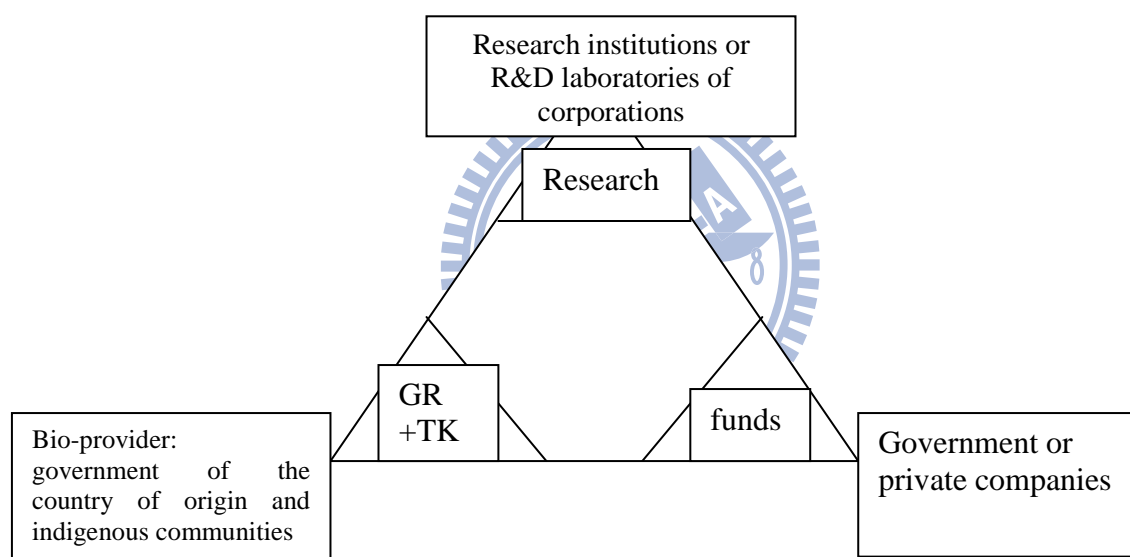
²⁰² «Avoiding the costs associated with self-help is actually a common justification for legal rules that might on the merits be hard to explain. Patent law certainly benefits from this kind of second-best story, a story where trade secret protection itself plays the role of costly foil» (Lichtman D., "How the Law Responds to Self-Help" (2004) U Chicago Law & Economics, Olin Working Paper No.232.)

IV. A proposal of an optimal model of TK licensing agreement

1. Mechanism of collaboration

The proposed mechanism (see **Fig.8**) aims, firstly, to ensure protection of interests of all stakeholders, and secondly to enhance the efficiency of the cooperation for the mutual benefit of all parties.

Figure 8. The proposed mechanism of collaboration



Bioprospectors are represented by research institutes and corporations' R&D laboratories, supported by private or state funds. Bioprovitors are represented by government of the country of origin of genetic resources and indigenous communities – the holders of associated traditional knowledge. It is important that TK-holders (or their representatives) immediately involve into the bioprospecting agreements from the

negotiation stage in order to protect their rights over TK and to guarantee benefit sharing derived from the use of this knowledge.

All sides of collaboration should have good preparatory work prior to signing a contract. Bioprospectors should fully inform local communities about all the important issues regarding a project (purpose of the use of TK, drawbacks and influences, patent application intention, etc.) and get formal prior informed consent. Indigenous peoples are advised to form well-organized unions to represent the interests of all TK-owning communities related to the project.

If indigenous communities manage to secure their TK as trade secret (know-how), then they can sell or license their knowledge and get benefits separately from the government, that collects royalties for the transfer of genetic resources only. Ownership permits TK holders to enjoy the benefits from TK commercialization. Contracts purely for traditional knowledge can become the threshold of bioprospecting agreements or the supplement to them.

The proposed contractual arrangement provides bioprospectors and biosuppliers with a guideline for establishing an effective collaboration that will result in a greater balance of bargaining powers and will satisfy the interests of TK-holders and TK-receivers.

2. TK licensing agreement

The TK licensing agreement is shaped basically like any IP licensing agreement, but due to some special characteristic of TK and TK holders,

it has certain other features as well. The general structure of the agreement is²⁰³:

- a) Recitals
- b) Definitions
- c) Duration
- d) Prior Informed Consent
- e) Warranties and Representation
- f) Rights and Responsibilities of the Parties
- g) Intellectual Property Rights
- h) Benefits and Royalties
- i) Sub-Licensing
- j) Confidentiality
- k) Penalties
- l) Jurisdiction and Governing Law
- m) Signatories



a) Recital: Parties to a Contract

The main parties are TK-recipient or licensee (research institutes, commercial or industrial partners) and TK-suppliers or licensor

²⁰³Byrne N., McBratney A., *Licensing Technology*, (Bristol: Jordan Publishing Ltd., 2005)

(indigenous community or their representatives). On the one hand, pushing legal entities and researchers interested in TK collecting to conduct any work together with government and national research institutions of the country of origin of TK holders would help to coordinate the activities among the parties and assure (guarantee) equitable benefit sharing. Furthermore, companies themselves are usually not eager to deal directly with “uneducated”, “non-developed” indigenous communities. Also a TK “accessor” can be required to obtain authorization of the appropriate local (government) authorities. But, on the other hand, this type of mandatory requirement may unduly restrict bioprospecting and related research and development activities.

b) Definitions

The contract should provide clear and objective definitions, especially regarding such terms as “traditional knowledge” and “indigenous community”. The expansive definition of them may raise lots of disputes. For example, the definition of traditional knowledge should not include too wide a range of information and activities. In our research we limited it to genetic resources association (mainly medicinal knowledge). The contract may also include TK derivatives. Therefore, it’s advised to specify them, as they make an already vague TK more uncertain.

The term “indigenous community” also needs special care. It is hard to give such a universal definition of the term “community” that will fit all potential partnerships and that would satisfy all the stakeholders. It’s

recommended to give the accurate name and location of an indigenous community to eliminate subsequent arguments about TK owners.

In the PIC clause the term “access” to TK should be defined clearly too: whether or not it includes acts taking place years after the initial access and procurement of the resources are made; whether or not it includes scientific research and development work that goes well beyond the typical meaning of “access” to these resources. This term should not be construed in a very broad manner to potentially include down-stream inventions that may be subject to patent or other IPR protection due to the inventive activity of a third party.

Clarity on these matters is of paramount importance. Otherwise unnecessary disputes will provide disincentives for companies and good-faith researchers to perform bioprospecting and reduce incentives for innovation and consequent benefit sharing.

c) Duration

The parties may establish a timetable of TK transfer, with certain milestones that should be met, or with subsequent obligations such as an agreement to negotiate further terms in the event, for example, if a product derived from the use of TK is approved for commercialisation. The parties may also decide whether the agreement is renewable or not.

d) Prior Informed Consent (PIC)

In this section a bioprospector provides the TK holder with sufficient information on key elements, purposes, risks and implications of the research and other activities concerning TK, including possible uses of the TK, and the value thereof, where applicable PIC is the important part of collaboration between bioprospectors and indigenous communities. The main purpose of PIC is to identify risks of using the TK in projects carried out by bioprospectors. Who is authorized to give prior informed consent: government agencies or indigenous communities? CBD Article 8 (j), COP Decision VI/10²⁰⁴ strongly encourages (and most countries recognize at some level) that PIC must be obtained from indigenous communities. It's obvious that from the point of view of the bioprospector, to get consent from governmental authorities is easier than from "uncoordinated" indigenous communities. Moreover it can happen that traditional knowledge belongs to a group of communities that live separately from each other, then the transaction costs of obtaining PIC from all these communities are too high. The question is whether a bioprospector has to get the PIC from all indigenous communities who live on the territory of bioprospecting and possess necessary TK or just one of them. In our opinion the burden of getting PIC from TK holders is already heavy enough. A bioprospector needs to get consent just from one particular community at issue within the territory of GR and associated TK collection. Otherwise it will "kill" all bioprospecting incentives. Another solution is when dispersed indigenous communities form

²⁰⁴ Convention on Biological Diversity, Sixth Conference of the Parties , Decision VI/10, UNEP/CBD/COP/6/20, Hague, 7-19 April 2002, available at <http://69.90.183.227/doc/decisions/COP-06-dec-en.pdf> (last accessed 20.08.2011).

organizations of their representatives like the Aguaruna people in Peru and bioprospectors get PIC not from the community but from such organizations.²⁰⁵

Another problem is whether it is legitimate to get PIC from only one member of an indigenous community. Will it be legally and ethically enough to ask consent from, for example, a healer or shaman alone? As Rosenthal²⁰⁶ notes the TK, on the one hand, can be widely and openly shared; and, on the other hand, be privately held (for example by a healer or a shaman in a tribe). Each community has its own restrictions on the possessing, spreading and use of traditional knowledge and punishments for violations of these restrictions. So it seems to be appropriate to be aware of TK related regulations inside a particular community and, according to them, ask for PIC. As Peigi Wilson²⁰⁷ in his “*Indigenous and Local Communities: Community-Level Prior Informed Consent for Accessing Traditional Knowledge and Genetic Resources*” says about impossibility of the universal, “one size fits all” process of obtaining PIC. But he also points out one common approach – respect.

e) Warranties and Representation

²⁰⁵ Lewis&Ramani, *supra* note 31.

²⁰⁶ Rosenthal, *supra* note 60, at 395.

²⁰⁷ Wilson, «Indigenous and Local Communities: Community-Level Prior Informed Consent for Accessing Traditional Knowledge and Genetic Resources», in M. Bellot-Rojas and S.Bernier (eds), *International Expert Workshop on Access to Genetic Resources and Benefit Sharin, Records of Discussion* (2004) 301, available at <http://www.canmexworkshop.com/documents/papers/III.4.2.pdf> (last accessed 20.08.2011).

This clause delineates the “rights” of owners of TK. Unlike IP licensing agreements in TK licensing the indigenous community can’t warrant that the TK in question will not be “claimed” by other communities that share the same knowledge. This includes the right to “deny access” by other communities without taking into consideration the consent that is given by the community-party to agreement. This clause aims to reflect the ability of an entity to gain access from one community without having to confirm access from any other community that may claim ownership rights in that same knowledge. If disputes arise among different communities as to ownership of TK, it should not affect a good faith entity that relies on legitimate consent from a recognized community that grants access.

f) Rights and Responsibilities of the Parties

In this section parties state their obligations and rights. Thus, for example, communities may invest themselves with a right to control how their knowledge will be used. The obligation may be imposed on the bioprospector to give a periodical account to the TK holder, in general terms, on the progress made in research and industrialization and the marketing of the goods developed on the basis of the licensed indigenous knowledge. It should be expressly stated if the contract contains a reserved rights obligation.

Here it is important not to make highly restrictive and discriminatory requirements to research and commercial entities that could limit their incentive and ability to engage in meaningful research and development partnerships and activities.

g) Intellectual Property Rights

The main purpose of this provision is to stipulate whether the community will own any intellectual property rights created from the traditional knowledge. In the early stages of a research relationship there may be no IP rights. In that case the agreement may focus on non-IP related benefit-sharing, such as technology transfer, training and education. If the planned research activities result in the creation of any derivatives, the provision in question should make it clear who will own them, or any IP flowing from them.

After product commercialization, should the need arise, the parties may agree to review the terms and conditions (including consideration of the ownership of IP, right to license the IP, benefit-sharing arising out of any licensing agreement etc.). One of the possible solutions regarding IP ownership is joint ownership, if the legal system in the country in question allows it.

The agreement may also set out the copyright provisions covering any manuals or other documentation received, and used, as part of the licensing package.

h) Benefits and Royalties

This clause specifies the payments that the indigenous peoples will receive for the use of their TK and TK derivatives. The indigenous community should negotiate the amount and form of compensation the TK-recipient will pay to use the knowledge. The compensation may take a form of a royalty for each unit of the product sold, a lump sum paid in

advance or a fixed payment for each year of the agreement. The royalties shall include an initial payment or some form of immediate, direct compensation to the indigenous peoples, and a percentage of the value of the sales resulting from the marketing of products developed on the basis of the said TK.

i) Sub-Licensing

This provision states whether or not, and on what conditions, a sub-license can be granted so that a third party may also use the TK in question. Any dealings with a third party by a bioprospector should guarantee the security and respect of the community's traditional knowledge.

j) Confidentiality

A confidentiality or non-disclosure provision can be a vital tool for ensuring that the obligation of confidence is established. For example, in appropriate circumstances the information provided by a traditional healer may be viewed as a trade secret. Parties may also need to consider the role of customary laws and practices when accessing such information, and seeking to enter into formal agreements, with traditional healers or their associations.

Indigenous communities in return have to maintain secrecy about all information regarding any activities held by the research and commercial partners after they get access to TK. The main source of this information is prior informed consent. The principle of confidentiality plays a central role in the patent system and the leaking of any confidential information

into the public domain can affect the securing of future patents. To maintain confidentiality is also vitally important at the stage of product development and marketing, as commercial secrets and know-how may be involved.

In addition, pharmaceutical companies and research institutions while contracting for the disclosure of TK may include provisions prohibiting TK holders from sharing that same knowledge with the third party for a set period of time. In such a case, the contract will look like an exclusive licensing agreement where the exclusivity is ensured by remuneration for indigenous people and thus provides the company or researchers with the competitive advantage of more exclusive time with the knowledge²⁰⁸.

k) Penalties

The penalties should be reasonable. The significant penalties included in the contract for potential violations may harm the desire of innovative biotechnology companies to partner with local institutions, indigenous and other traditional communities in a way that will be beneficial for all parties.

l) Jurisdiction and Governing Law

Obviously TK related laws are more developed in the countries where this TK is originally found. Some countries, especially biodiversity-poor ones, have a weak legal system of TK protection, if any at all. That's why it is reasonable that the agreement in question is governed and construed in accordance with the laws of the country of TK origin. If disputes

²⁰⁸ Bates, *supra* note 46.

between parties do arise they are also solved in the country of TK-suppliers. If TK, after transferring from the TK-holder to the TK supplier, is exploited outside the country of origin this provision gains in importance.

m) Signatories

Either a juristic or natural person can be the signatory of a contract. A bioprospector is usually a legal entity, and its representative (for example, a president or vice-president) is a competent signatory to any contract. As for the TK-holders, an indigenous governing body or community organization, or a NGO acting as an agent to protect community's interests and rights are entitled to sign a contract. An indigenous community may also identify an elder or other member who records the TK in question in a fixed form as if he were its creator.

3. Conclusion

Summarising the above analysis it is uncontroversial that privately contracting for traditional knowledge can give sufficient protection to this knowledge and their holders and also to provide benefits for both parties to the contract. Contractual arrangement is a flexible instrument of TK protection, though it has some drawbacks, such as an imbalance of bargaining power and the difficulty of enforcement.

V. Conclusions

The protection of traditional knowledge is progressively taking a center stage in global discussions²⁰⁹. During recent decades, research and new product discovery in such biotech-related industries as pharmaceutical, phytomedicinal, nutraceutical and herbal, has increasingly relied on the TK of indigenous communities in substantial ways²¹⁰. The interdependency between drug discoveries and TK makes the participation of indigenous communities in bioprospecting processes essential. On the contrary in many cases research institutions and pharmaceutical corporations not only access and use TK, and patent active compounds derived from the knowledge, but they neither inform TK-holders thereof nor share benefits with them. Sometimes after getting patent rights bioprospectors prohibit indigenous communities from usage of their own knowledge.

For aboriginal communities TK consists of more than the inventions and creative works, it is the expression of the human soul in all its aspects, as well as the foundation for the economic, social and spiritual growth²¹¹. Traditional knowledge constitutes a tremendous value both for indigenous and non-indigenous societies. The sustainable use, protection and preservation of it is of vital importance.

²⁰⁹ Alpin T., Davis J., *Intellectual Property Law: Text, Cases, and Materials*, (New York: Oxford University Press, 2009).

²¹⁰ Gelvina Rodriguez Stevenson, "Trade Secrets: the Secret to Protecting Indigenous Ethnobiological (Medicinal) Knowledge", 32 *New York University Journal of International Law and Politics* (summer 2000)

²¹¹ Anaya, *supra* note 159.

The main issue is that there is still no any workable legally binding international regime of TK protection. Until such regime is established, indigenous peoples have to use existing legal instruments currently available to secure their knowledge. As it was argued and proved in the dissertation contractual agreement is one of them.

The present research has enriched a limited information body related to TK contractual arrangements. Thus several ICBG bioprospecting cases that implied private contractual arrangements were thoroughly analyzed. The main goals of the ICBG are to examine the medicinal potential of the earth's biodiversity, to support its conservation and to promote human health and economic development by means of collaboration assistance between the different parties involved. It also aims to enhance the efficiency of this cooperation for the mutual benefit of all parties. These parties include pharmaceutical companies and research entities on one side and TK -holders on the other. ICBG projects are characterized with indigenous peoples' immediate involvement (for example through indigenous NGOs or local unions) in the bioprospecting agreements in order to protect their rights over their TK and to guarantee benefit sharing derived from the use of this knowledge. Both sides of ICBG project - TK owners and bioprospectors - have good preparatory work been done prior to signing a contract. Bioprospectors inform local communities about all the important issues regarding a project (purpose of the use of TK, drawbacks and influences, patent application intention, etc.) and get formal PIC. Indigenous peoples as a rule form well-organized unions to

represent the interests of all TK-owning communities related to the project.

To fulfill the research objectives, the depth analysis of advantages and disadvantages of private contracts was conducted in the dissertation. One of the main advantages of the private contractual arrangement is that it provides both national and cross-country protection of TK-holders' rights. It also assures fair benefit-sharing, derived from the indigenous knowledge. Contract is flexible and transparent.

One of the main drawbacks of the private contracting is unequal bargaining power: indigenous communities are always a weaker party to a contract. Recognition of intellectual property rights of indigenous communities over their traditional knowledge can substantively enhance their bargaining power. The problem is that indigenous peoples' ownership over TK is not recognized world-wide. Though the national laws of some countries with rich genetic resources and traditional knowledge such as Brazil, Panama or Peru have recognized indigenous communities' intellectual property rights over TK, for bioprospectors traditional knowledge is a common property.²¹² The ownership ensures that indigenous peoples can engage with the state and third parties as active stakeholders rather than as passive beneficiaries. The dissertation suggests to use existing IPRs, i.e. trade secret, and secure the TK transfer by licensing agreement between bioprospectors and TK-holders. But unfortunately applying trade secrecy protection brings constrains and

²¹² Bratspies, *supra* note 12, at 320.

limits traditional knowledge to that one which is undisclosed to indigenous world.

Other research objectives were to provide an effective mechanism of collaboration between bioprospectors and biosuppliers and to propose a guideline of an optimal model of TK licensing agreement. In order to adequately protect TK-holders' rights it is suggested that the mechanism of bioprospecting process should include indigenous peoples or their direct representatives. TK-holders should be actively involved into bioprospecting and get strong support of the government in form of legal consulting and securing transactions with bioprospectors. Due to the time and scope limitations the role of the government was not scrutinized in details. Therefore it is suggested that this part would be described and analyzed in the future research works.

Contractual arrangement is not a panacea, therefore it is essentially important that legal scholars continue elaborating new instruments and techniques that are more suitable for the TK protection.

VI. Appendix

Table 1. Number of patent applications by leading countries (2005-2009)

	2009		2008		2007		2006		2005	
	Non-resident	resident	Non-resident	Resident	Non-resident	resident	Non-resident	resident	Non-resident	resident
USA	231,194	224,912	224,733	231,588	214,807	241,347	204,182	221,784	182,866	207,867
Japan	53,281	295,315	60,892	330,110	62,793	333,498	61,614	347,060	59,118	367,960
China	85,477	229,096	95,259	194,579	92,101	153,060	88,183	122,318	79,842	93,485
Republic of Korea	36,207	127,316	43,518	127,114	43,768	128,701	40,713	125,476	38,733	122,188
Germany	11,724	47,859	13,177	49,240	13,139	47,853	12,573	48,012	11,855	48,367

Source: WIPO Statistics Database, January

2011

Table 2. The number of Patent applications in the field of biotechnology and pharmaceuticals by leading countries (2003-2007 total)

	biotechnology	pharmacueticlas
U.S.	61478	102133
China	12,177	43,508
Japan	21983	27685
Germany	12402	22203
Switzerland	4060	13793
United Kingdom	6103	11222
France	5154	10780

Source: WIPO Statistics Database, September 2010

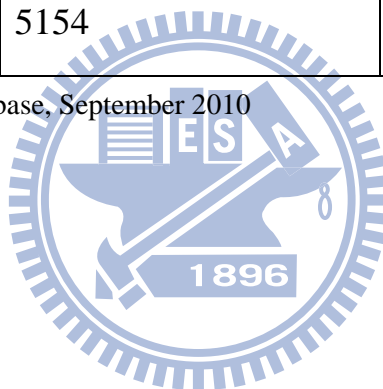


Table 3. ICBG Projects' Main Features Comparison

	Peru –ICBG	Maya –ICBG	Vietnam-Laos - ICBG
Time of execution	1994-1999	1998-2001 (was terminated)	1998-2003
Most important goals	To develop new therapeutic methods against infections and chronic diseases, biodiversity conservation, community development	To discover a drug from the plants and macrofungi	To discover biopharmaceuticals, develop drugs from cancer, AIDS, malaria and other diseases that effect central nervous system, biodiversity conservation, aiding economic development of local communities
Partners of the collaboration	<p>Research: Washington University, 2 Peruvian universities;</p> <p>Industry: Searle-Monsanto Company;</p> <p>Indigenous people: Aguaruna organization</p> <p>OCCAAM, NGO CONAP.</p>	<p>Research: University of Georgia, local institution ECOSUR, Molecular Nature Ltd;</p> <p>Industry: small pharmaceutical and botanical company;</p> <p>Indigenous: non-profit organization PROMAYA</p>	<p>Research: University of Illinois, Glaxo Welcome Research and Development Ltd, The Vietnam National Centre for Science and Technology, Cuc Funong National Park (Vietnam), Traditional Medicine Research Centre (Laos)</p> <p>Funding: U.S. government</p>

Representation and self-organization of the indigenous communities	Represented by well organized, well-functioning and well-prepared NGOs; had their own counsels	PROMAYA was a newly established organization, not very developed and united	no data
The involvement of the indigenous peoples	Participation in PIC negotiation process	Not all the communities were involved and formally informed	No direct and formal involvement of the communities or their representatives. PIC requirement
Model of TK transfer	Know-how license	Rather integrated and sophisticated contractual agreement	No data
Benefit sharing for the indigenous communities	Advances, milestones, royalties shared with other partners	Reasonable income from surprising discovery rates, joint ownership over patents.	50% of the royalties
Government involvement	Peruvian and U.S. government were involved to provide legal advice	No data	Partner to the contract

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