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INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY IN BRAZIL: CONSERVATION, SUSTAINABLE USE AND PROTECTION OF THE INDIGENOUS RIGHTS

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Acknowledgments

Spending the Fall 2000 academic semester at George Washington University,
hosted by the Institute of Brazilian Issues, was a remarkable experience that I will keep for life.
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1 INTRODUCTION

When they were created, in a more modern fashion, in Great Britain, patents were monopolies given to inventors, particularly in the fabrics industry, in order to attract them to British territory, where they should invest and apply their knowledge. Patents were, therefore, an economic policy tool for the country, which, in return to the conceded privilege, received the inventor's decision to use the innovation in its market and to freed its use after the monopoly validity period[1].

In its basis, then, prevailed the understanding that the guaranty of privilege for the inventors would stimulate the creation of technology and its diffusion[2].

Since its origin, a patent corresponds to a contract between the government and the inventor by which the public power assures temporary monopoly of production and commercialization in the country to the inventor, requiring from him in return:

a) complete disclosure of the invention. Even if the production and commercialization of the invention are not allowed by third parties during the privilege period, the invention may be used as a resource for local research and development. It may serve to increase the local knowledge and to save money and time by skipping equal steps already taken by the inventor; and
b) local manufacturing of the invention. The patent holder must produce his creation in the country that gives him the monopoly in order to allow the country to appropriate benefits and improve the economy by the use of its human and natural resources.

As it is pointed out in a Center for International Environmental Law – CIEL's paper:

[1] "Since their origins, invention patents were conceded for economic development goals, promoting the diffusion of the technical-productive knowledge and local industrialization. To imagine a concession of patents to promote industry in another country is a economic incoherence – except in the case of recent economic integration areas. This is a naif position, even no being ingenuous" (A. L. Figueira Barbosa, *Importacao, Trabalho Obrigatorio, Caducidade e Licenca Compulsoria*, in Revista da ABPI, n. 25, nov/dec 1996).

> *Historically, intellectual property rights (…) have been extended to inventors and creators as reward for innovation, and as an incentive to disclose information to the public and promote innovation by others. Intellectual property in some form is almost universally recognized as an essential policy tool in market economies. The benefits to society of the legal right are, however, carefully balanced against the cost to society of granting it*[3].

Through the classic approach of patenting, the simple supplying of the host market by exportation does not fulfill the patent system requirements. That is the touchy point for criticism by the current market view approach of patenting that considers that the only flow of goods, capitals and services is, itself, sufficient to increase the economies, no matter the local production.

Manufacturing of patented products in the country that gives the privilege appears as a point of permanent conflict between countries that give patents and the patent holders. The interests of the patent holder are to obtain maximum profits and market control. He shall apply for patenting in all the countries he considers will be a promising market for his product, even though, he will produce only in one or two countries where he may have his factory units. Then, if possible, he will concentrate the production in his origin country or other country that gives him an incentive and will try to guarantee a protected market in the other countries for his exportations[4]. On the other hand, countries that grant patents need the local production to help empower its economy. This is why, in a broad sense, all the national regulations require that the manufacturers locate inside the national borders[5].

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[2] MASKUS, Keith E. – *Intellectual Property Rights in the Global Economy*.

[3] CIEL – Center for International Environmental Law, *The 1999 WTO Review of Life Patenting Under TRIPS – Revised Discussion Paper – November 1998.*

[4] In Brazil, imports of medicines increased from US$ 50 million per year before the Patent Law to the amazing amount of US$ 1,3 billion per year after the law, according to Latin American Pharmaceutical Industry Association (ALIFAR, *Declaracao de Guaruja*, May 27th, 1999).

[5] This is not a complete true statement today. Also, there are benefits to the country receiving the imports, including lower costs, since it may be inefficient to manufacture in every country. In fact, this will normally be the case for many manufactured items. Brazil now exports manufactured goods to other countries under patent protection there without manufacturing in those other countries.

In the hypothesis of not fulfilling the local production requirement, directly or through licenses, the patent holder, legally, goes into the risk of having his patented invention being produced by another person, after a concession of a compulsory license by the Government, or having his patent extinct by lack of production, falling into public domain[6].

This is the essence of the battle of interests between the patent holders and the countries that host them. This conflict has been in the realm of the national regulations for a long time. One could say that it is the main issue in patent regulations, and it has been object of tough discussions and has suffered important changes, influenced by the modern trade model.

To discuss which would be a healthy equilibrium between these two interests – trade improvement and local development – in order to perform a good patent law, mediated by good economic principles, would be the hidden objective of this study. More explicitly, however, this paper will deal with two specific aspects of new topics on the intellectual property rights. First, the discussion about intellectual property and the use and conservation of biodiversity; second, the building of the new intellectual property system to protect the indigenous and local communities' rights over their knowledge.

Both are in the threshold of intellectual property regulating task, world widely, and Brazil has played a protagonist role in this field, since the negotiations of the Convention on Biological Diversity. Also, to reinforce the attention given to this subject, right in this second half of 2000, the Brazilian Congress is discussing a Brazilian regime of access to genetic resources, which defines the key issues on each one of those questions.

Before reaching that, notwithstanding, we intend to discuss shortly some other issues related to intellectual property regulation, just in order to have a big picture of

[6] Patent extinction for non-working (caducity) is not part of Brazil's law today.

the subject. This gives an overview about the international arena and a brief description of Brazilian recent pieces of legislation.

2 INTELLECTUAL PROPERTY RIGHTS AND THE GLOBALIZED ECONOMY

In the traditional way to regulate intellectual property rights, bound by the Convention of Paris, each country has the sovereign right to regulate the issue[7] (and, by logical deduction, they must regulate in the pursuit of its own interests, which would be, in most cases, helping development). This is the spirit of the Convention of Paris, signed in 1883, that poses two basic principles:

a) **Principle of national treatment**, by which each party has complete liberty to define its patent regulation, since it does not make any discrimination between its citizens and other countries' people. Thus, it is for each country to determine which products are or are not patentable, the time limit for the patent monopoly, the criteria for the concession of the warranty, and so on, since the norms are applicable to everyone, nationals or foreigners.
b) **Principle of priority**, which gives the patent applicant a time limit of twelve months to ask for patent in any of the other member countries of the Convention of Paris. During this time span, any patent application from a third person shall be not taken into consideration.

As time passed, and economies changed, the flow between countries increased, the world reorganized itself in a global way, the patent system also went through crucial shifts. In electronics, for instance, the speed of innovation has been so high that when a patent is given, the invention is already obsolete. In this field, with that characteristic, and since the products are not easily copied, there are practically no patent applications. In this area, technology transfer has been made through contracts that do not involve patents. In the decade of the 80s, 70% of international

[7] MASKUS, Keith E. – *Intellectual Property Rights in the Global Economy*, p. 15

contracts referred to non-patented technologies. In a recent public occasion, Robert Sherwood pointed out that *"the corporate lawyers and licensing managers – the people closest to creation and transfer of technology – said over 60%, with many of them reporting 90%, or more [represented the portion of technology which have been transferred from one place to another depending on industrial secret protection]"*[8], which re-emphasizes the importance of the industrial secret. Surely, this does not diminish the importance of the patents for the whole economy, and for specific strong sectors. It just shows a shift in the behavior of intellectual protection.

However, changes did not rely only in the technology side. Market, commerce, services, all the soft side started to be increasingly more important to the economy, replacing traditional sectors like raw material exploration and goods manufacturing. In this regard, the patent system showed up and was mechanically transferred to the new informational world and began to be used more and more as a tool to protect the interests of those agents of commerce and services. Material property, very useful to tie natural resources in the old economy, has been quickly giving in to intellectual property, as a measure to pay the new investments, mainly founded in knowledge, information and technology.

As remarked by CIEL:

> *If we are indeed becoming a society in which information is the most valuable resource, then an overriding question will be, who controls the information? Intellectual property law, which defines ownership rights over information, is one of the main ways our society resolves these questions.*[9]

And continues in the same paper:

> *Today, the balance seems to be shifting. Intellectual property laws are defined through closed, secretive international negotiations dominated by industry – and are then brought to national legislatures as faits accomplis,*

[8] SHERWOOD, Robert. Presentation at Associacao Brasileira de Propriedade Intelectual (ABPI) Seminar
[9] CIEL – Center for International Environmental Law, *The 1999 WTO Review of Life Patenting Under TRIPS – Revised Discussion Paper – November 1998*.

> *without democratic deliberation. Combined with the technical, arcane nature of the intellectual property legal specialty, this has helped corporate interests to avoid public scrutiny and expand their control over developments in applications such as electronic information, biotechnology or pharmaceuticals. Industrial country governments promote corporate interests in expanded intellectual property rights in the name of maximizing national competitiveness in a global marketplace. The resulting boon to private investors – embodied in international treaties such as the trade agreements administered by the World Trade Organization – has been called an "information land grab"*[10].

The fact was that the accelerating globalization through trade, foreign investments and licensing came into conflict with the Convention of Paris regime, based strictly on national or territorial laws. World, pushed by the United States, needed a regulation on an international scale[11].

This was the big picture in which intellectual property rights were brought to GATT discussions and negotiations that finished up in World Trade Organization (WTO) and Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). This last one treaty, as a part of the whole negotiations that leaded to WTO, replaced, in many senses, the former and still existing World Intellectual Property Organization (WIPO) as the international organization for this area[12].

Basically, what was done in 1995 with TRIPS was to eliminate the Convention of Paris principle by which each country has the right to establish its own rules. Now, since TRIPS, countries must grant basic legal patterns, with no exceptions, only certain possible delays in put in validity for least developed countries. In a few words, the main innovations about this, and that are important for this study, are: (a) there are not anymore non patentable area, all inventions and creations must be able to be protected; and (b) regarding living forms, at least micro-organisms must

[10] Idem.
[11] MASKUS, Keith E. – *Intellectual Property Rights in the Global Economy*, p.16
[12] WIPO was never designed to set norms, only to aid countries in administering their IPRs administrative offices and to offer advice regarding legislative drafting. WIPO had and has no enforcement responsibilities. WIPO could have been the forum within which the TRIPs, or something like it, was negotiated and agreed upon, but this never happened, and so it was done within the old GATT mechanism as a trade-related treaty.

be patentable, and countries will also adopt, if not patentable, a *sui generis* system for plants and animals.

> *The TRIPS agreement requires countries to recognize patents on most products and processes, including pharmaceuticals, modified microorganisms and "microbiological processes" (Article 27.3.b). Currently, however, it does not require countries to recognize patents on plants or animals, or "essentially biological [but not microbiological] processes for the production of plants or animals" (ibid.). Under Article 27.3.b of the TRIPS Agreement, each country has the discretion whether to recognize these patents. Countries may protect plant varieties either through patents or an "effective* sui generis *system" or both. This exception exists because many other countries rejected the U.S. demand for patenting plants and animals, on economic, legal or ethical grounds*.[13]

On the other hand, given the recent pressures in the last international events, it seems that the fundamental issues of TRIPS, and whether TRIPS as it is helps promote the economic development of developing countries, and enable countries to strike an appropriate balance between public interest and private rights is now in the process of getting on to the agenda of the World Trade Organization.

And actually, while in the past, the U.S., Europe and Japan used the TRIPS meetings to promote the idea of "review" for enhancing the standards of protection, and need for more protection for property holders, the situation of imbalance and need to remedy them is now being forcefully put forward and argued by a number of developing countries.

Carlos Correa[14] resumes the arguments of these segments in the developing countries. About trade, it is argued that the introduction of patents without the obligation to industrially exploit the invention in the country of registration, is likely to generate or expand trade deficits, as a result of an increased volume and eventually higher prices for imported finished products and active ingredients. Regarding research and development, in a field like pharmaceuticals, with high economies of

[13] CIEL – Center for International Environmental Law, *The 1999 WTO Review of Life Patenting Under TRIPS – Revised Discussion Paper – November 1998*

scale in R&D, patents are very unlikely to stimulate R&D by local or foreign companies in developing countries. R&D costs are not affordable to the former, while the latter tend to concentrate R&D in a few locations in industrialized countries.

About local production, Carlos Correa affirms that the production of pharmaceuticals by local firms will be limited to generic drugs. Foreign patent owners will have the choice, in principle, to produce locally or to import the product or the active ingredients. According Correa, it seems that the impact of patents on investments and production will depend on the conditions of each market, but most probably the growth prospect of local firms will be modest at best, unless they are able to participate in the most dynamic segments of the market under licensing arrangements.

Analyzing technology transfer and balance of payments, Correa considers that the granting of patent protection may have an ambivalent effect on the transfer of technology. On the one hand, it will reinforce the power or the patentee to decide how to exploit its technology and whether to confer licenses or not to other parties. On the other hand, the existence of such protection may be regarded as a condition for such a transfer to take place. According to Correa, studies by the World Bank have indicated a possible important increase in payments due to royalty and profit remittances.

At last, one could agree with the comments by Keith E. Maskus, that TRIPS is an agreement of substantive minimum standards in all areas of intellectual property protection. Thus, according to him,

> *TRIPS is the most significant international undertaking on IPRs in history. Because it tilts the global balance toward stronger rights of information developers, it promises to effect a short-term distribution of income in their favor from information users, in both developed and developing countries. Over the longer term, because TRIPs fundamentally alter incentives for international commerce, imitation, and innovation, it should generate dynamic benefits with a*

[14] CORREA, Carlos, “Implementing TRIPS in developing countries”.

broader scope of winners. To the extent that additional social costs could emerge, it will be important to develop policies to manage such costs[15].

3 NEW BRAZILIAN LEGISLATION ON INTELLECTUAL PROPERTY RIGHTS AND MAIN NEW WORLD TRENDS

This chapter represents a quick overview about the very important changes in Brazilian legislation on IPR in the past few years. Besides mentioning the regulation already in force, we would also cite, with the same kind of brief scope, the bills under discussion before the Brazilian Congress. We finish the chapter with a notice, not in depth again, about the new trends and practical discussions about the issue on the world scenario.

3.1 Brazilian laws and decrees

In the new Brazil legal framework, the major piece of legislation is the Law 9.279, of May 14th, 1996, the quite known Brazilian new Patent Law. It comprises a complete code of industrial property and replaced the existing Law of 1971. It establishes the rules for patents, protection for models of utility, industrial design, trademarks, geographic indications; time-limits of proctetion for each one of them; voluntary and compulsory licenses, rights of the employers and employees; technology transfer and register at the official agency (Instituto Nacional da Propriedade Industrial – INPI); unfair competition; and criminal and administrative sanctions.

In a few words, this text fully fit the law under the paramethers of TRIPS, finally firmed by that same time. In this sense, one of the main changes was that one related to the TRIPS command to cover by patent all kind of inventions, that is, the change that extended patentability to microorganisms, medicines and chemicals. These changes are focused in the last part of this paper.

[15] MASKUS, Keith E. – *Intellectual Property Rights in the Global Economy*, p. 26

Following the Law 9.279/96, Brazilian Government published Decree 2553, of April 16th, 1998, that disciplines a few articles of the Law and establishes norms about patents os interest for national defense and incentives for public servants who develop inventions.

Afterwards, it was issued Decree 3201, of October 6th, 1999, which regulates the concession of compulsory license, in the case of national emergence and public interest.

More important, since December 1999, Government has been monthly re-issuing the Provisional Decree 2014, which defined the transitional treatment to adequate the new patentable material (medicines and chemicals) to TRIPS umbrella. The problem was due the to the fact that the new Patent Law was approved before TRIPS entered in validity.

Outside the patent law system and coming after that, a few other crucial pieces of legislation were added. Firs of them was the Law 9456, of April 25th, 1997, which establishes the rules of protection of plant varieties. It defines the requirements for a variety to be protected, the time-limit of protection (15 or 18 years); proceedings for compulsory and voluntary licenses; rights of employers and employees; and administrative sanctions. The law also creates the National Service of Protection of Plant Varieties (Servico Nacional de Protecao de Cultivares – SNPC). This law was detailed by the Decree 2366, of November 5th, 1997.

In February 19th, 1998, two copyright laws were published in Brazil. The first one was the Law 9609, which regulates copyright over computer softwares. It fixes the authorship rights; the moral and patrimonial rights; the time-limit of protection (50 years); the optional register; the rights of employers and employees (presumption of the employer); the guarantees of the users; voluntary licenses; contracts of licenses and royalties; technology transfer; and criminal and administrative sanctions. The Law was disciplined by the Decree 2556, of April 20th, 1998, which basically focus

on the optional registering at INPI, regulating the secrecy of parts of software that must identify the protected program.

The second law of February the 19th, 1998, was the Law 9610 that replaces the former legislation about copyright. It establishes the scope of the protection; the optional official register; the time limit of protection (70 years); it disciplines the transfer of rights; the connected rights (interpreters, producers); the right of association; and administrative sanctions. The copyright law also had a decree to detail it. The decree (2894, of December 22nd, 1998) creates a special seal, issued by the Brazilian federal revenue service (Secretaria da Receita Federal), as a control tool to manage the payment of copyrights due over audio-visual works.

The last piece of legislation already in validity is the Provisional Decree 2052 (published for the first time in late June of 2000). It is the current Brazilian regulation of access do genetic resources, which disciplines substantial parts of the Convention of Biological Diversity, and regarding the theme of this paper, defines two interfaces: firs it talks about the Convention's rule of benefit sharing with the countries, and patents and other property rights are very important components of those benefits to be shared; and secondly, it designs the major lines for the protection of indigenous knowledge biodiversity related, which is a kind of intellectual property rights. This subject has arisen a huge and tough discussion around the world, and it will be the theme of the last chapter in this study. For the moment is enough to say that, after eight years the Convention, Brazil do have a regulation, even being provisional. It recognizes the rights of the indigenous peoples and local communities over their knowledge; defines their participation in the agreements for use os the knowledge; establishes a general legalization of all uses prior to the day of the decree and the possibility of a registry to entitle the rights.

3.2 Bills of law in the Brazilian Congress

Besides the existing new laws that configure the new paradigm of the Brazilian IPR system, under TRIPS and the new economical policies, other proposals are still going on in Congress. Some of them represent real changes and complements to the system. However, despite their potential importance, provided they are not laws yet, we will only take an overview, aimed to help the reader if he wants to go further for details.

First, the Bill 1787/96 (from the Executive branch), regulates intellectual protection for electronic circuits. Like the other regulations on copyrights, its scope comprehends the proceedings, the titularity, the time-limit of protection, compulsory and voluntary licenses, public non-commercial uses and criminal and administrative sanctions.

About changes in criminal sanctions in offenses against copyrights, there are the Bill 2781/96 (from the Executive branch) and the Bill 3302/00 (of Representative Salomao Cruz, Roraima). Changes in criminal sanctions in crimes against trademarks are the focus of the Bill 333/99, of Representative Antonio Kandir (Sao Paulo).

Other proposals related to copyrights are the Bill 1553/99 (Representative Professor Luizinho, Sao Paulo), which determines the closing of the copyright revenue central office; and the bills 2300/00 (Representative Clementino Coelho, Pernambuco) and 2535/00 (Representative Valdeci Oliveira, Rio Grande do Sul) that both deal with protection of trademarks in the Internet.

About patents, current bills are 1338/99 (Representative Freire Junior, Tocantins) that aims to limit the patent duties for the Government owned pharmaceuticals laboratories, and 1922/99 (Representative Eduardo Jorge, Sao Paulo), which

relieves patent payments for products and processes related to AIDS treatment medicines.

About the scope of patent owner rights, there is the very controversial proposal introduced by Representative Alberto Goldman (Sao Paulo) that modifies one article of the Patent Law to allow parallel imports, also known as international exhaustion of the rights. It is the Bill 139/99.

3.3 Legal trends in the international context

As a closing remark to this chapter, we would like to point out some observed tendencies in the international context. This arena has become the place where more and more important changes have been taken. Once again, and at last, the considerations here do not intend to go into a deep analysis of the facts, but are only a brief notice to further research.

One first detected movement is toward the protection of intellectual property rights in the Internet environment. Things like the relation between marks and web site domains, control over circulation of intellectual and artistic works, responsibility of the Internet providers, and the hard question about the jurisdictions (political frontiers) are now under discussion. Currently, also, there is a panel between Canada and the European Union about revising exceptions and limiting patentability of computer software.

Discussions also continue about a review of protection of geographic indications established in Article 24.2 of TRIPS, and about protection of notoriously known marks, as in Article 6-bis of the Convention of Paris and in Articles 16.2 and 16.3 of TRIPS.

Another important trend in the international panorama is the protection of non-original data bases as a reward based in substantial investment.

A last aspect of TRIPS that was supposed to be discussed five years after its approval is related to protection of living forms inventions: patenting for micro organisms and the creation of a sui generis system to plants and animals, at least, according Article 27.3.b. A huge debate ensued. Many expected that there would be a strong push between countries that try to extend the patentability beyond micro organisms and those that want to restrain it, but actually, until now, the economical agenda has surpassed this point, and no decisions have been made.

4 INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY

Both issues – intellectual property rights and biodiversity – have had recent important developments in the international level. On the one hand, we have seen the wide spread of the rules of a globalized market economy, with the building of the World Trade Organization – WTO, and the adoption of the Trade Related Aspects of Intellectual Property agreement – TRIPS, which, for the first time, brings the regulation of intellectual property to the scope of the international trade. Such subject that was before considered essentially a matter of science and technology now is regulated by the amount of commercial profits that it can protect. But this is not the only innovation of TRIPS. More relevant to the environmental and biodiversity consideration the TRIPS obligation for each part to give patent to micro organisms, as well as to adopt a *sui generis* system for intellectual property on plants and animals.

Besides TRIPS, there are many other international and national initiatives that reinforce almost exclusively the market based model for the use of biodiversity resources. Among them, one can mention, for example, BIOTRADE, conceived by the United Nations Conference on Trade and Development – UNCTAD, which has

as its objectives *"undertake market research, disseminate market contracts, broker deals, and offer training in the technical and legal aspects of bioprospecting do developing countries"*[16]. The World Bank and the United States National Institutes of Health's programs, as well as the agreement Merck-InBio, in Costa Rica, could also be seen as political and legal mechanisms that push that model. All these initiatives could be characterized by giving strong importance to the classical tools of IPR, trying to apply patents and trade secrets to all resources, products, processes or components of knowledge, independently if they have or not specific conditions as a biological or traditional community resource.

On the other hand, there is the Convention on Biological Diversity – CBD, which, together with other protocols and soft law instruments, constitute the "biodiversity international regime", as called by some new international law practitioners. This new global regulation was a fruit of an increasing concern about the dramatic levels of loss of biodiversity caused by the new patterns of human behavior. The advent of the biotechnology, which could represent either a source of richness and a threat to the biodiversity, was also encompassed in the regime, limiting its possible bad effects and providing resources for the conservation activities.

Conceptually, biotechnology comprehends the set of technologies that are applied to living organisms, or to their parts, in order to create or modify products, enhance plants and animals, or develop or modify microorganisms for specific purposes. The largest advances in biotechnology are in genetic engineering, which consists roughly of techniques used to isolate genes, work and use them in other organisms.

The classic biotechnology, before the DNA manipulating age, used to use, even with human intervention, essentially the processes of natural biological activities in living materials, like fermentation, biomass production, and the use of breed techniques to enhance plants and animals.

[16] BELL, Janet, *Biopiracy's Latest Disguises*, in Seedling, June 1997, Vol. 14, N. 2, pp. 2-19

Then, a good point to start the core of this study is, therefore, to talk about the importance of the biodiversity and the need for its protection. A few extracts from a CIEL paper[17] can help on that.

> *Biodiversity makes up the structure of the ecosystems and habitats that support essential living resources, including wildlife, fisheries and forests. It helps provide for basic human needs such as food, shelter, and medicine. It composes ecosystems that maintain oxygen in the air, enrich the soil, purify the water, protect against flood and storm damage and regulate climate. Biodiversity also has recreational, cultural, spiritual and aesthetic values.*
>
> *Society's growing consumption of resources and increasing populations have led to a rapid loss of biodiversity, eroding the capacity of earth's natural systems to provide essential goods and services on which human communities depend. Human activities have raised the rate of extinction to 1,000 times its usual rate. If this continues, Earth will experience the sixth great wave of extinctions in billions of years of history. Already, an estimated two of every three bird species are in decline worldwide, one in every eight plant species is endangered or threatened, and one-quarter of mammals, one-quarter of amphibians and one-fifth of reptiles are endangered or vulnerable.*
>
> *Also in crisis are forests and fisheries, which are essential biological resources and integral parts of the earth's living ecosystems. The World Resources Institute estimates that only one-fifth of the earth's original forest cover survives unfragmented, yet deforestation continues, with 180 million hectares in developing countries deforested between 1980 and 1995. Forests are home to 50-90% of terrestrial species, provide ecosystem services such as carbon storage and flood prevention, and are critical resources for many linguistically and culturally diverse societies and millions of indigenous people.*
>
> *Overfishing, destructive fishing techniques and other human activities have also severely jeopardized the health of many of the world's fish stocks along with associated marine species and ecosystems. The Food and Agriculture Organization of the UN estimates that nearly two-thirds of ocean fisheries are exploited at our beyond capacity. Over one billion people, mostly in developing countries, depend on fish as their primary source of animal protein.*

The world response to this situation was the Convention on Biological Diversity. The main objectives of the CBD are to promote the conservation and sustainable use of

[17] CIEL, Biodiversity and Wildlife Program, http://www.ciel.org/bwp.html

biodiversity; to ensure the fair and equitable sharing of benefits that arise from that use; and to undertake the protection of the indigenous and local communities' rights over their knowledge associated with biodiversity. To accomplish these objectives, the CBD, besides other mechanisms, guarantees the observance of national sovereignty of each country over their biological resources, subject to national regulation.

All of those principles of the CBD are related to the field of intellectual property. Conservation and sustainable use of biodiversity, since that are related to new techniques on bioprospecting and to the use of biotechnology, requires, under the Convention, the observance of involved intellectual property rights. So, transfer of technology, including biotechnology, must be submitted to intellectual property rules. This could be considered a wedge of the market approach into the biodiversity regime, but, anyway, it is consistent with current WTO/TRIPS regulation. Adding to that, in order to implement these new kind of social, political and economical demands now embodied in the CBD, some improvements are necessary in the classical regulation of IPR and also the creation of new laws and treaties, widely known as "access to genetic resources laws".

4.1 Fair and equitable sharing of benefits from the use of biodiversity and transfer of biotechnology.

The rule for a fair and equitable sharing of benefits arises from the fact that the nations are sovereign over their natural heritage, which represents an immeasurable source of economical and strategic resources. Given the advance of biotechnology it would not be fair simply let this patrimony to be sampled, screened, and developed by private companies without any compensation for the nations that have kept and conserved the natural resource.

In order to implement this principle, the CBD establishes, jointly with the guarantee of national sovereignty by each country, that the access to genetic resources

between countries only can be done after the accomplishment of two mechanisms: prior informed consent (PIC) and mutually agreed terms (MAT). It means that a base of more equitable benefit sharing between the provider-country and the user-country must be established through these two instruments. Enforcing such rules means that countries should make deals and agreements based in national regulations. It means also that these understandings between countries (PIC and MAT) would involve partition of the patent or other intellectual property rights that would arise from the use of that resource. Therefore, application of PIC and MAT has direct implication on the intellectual property field and will start important negotiations when this regulation begins to be enforced.

Moreover, in order to strengthen those Convention rules, we assist now a growing trend to propose amendments to intellectual property laws. Basically, the idea is to ensure that applications for patents related to biological material bring a certificate that such material was collected according to the country's national regulation, which means that the rules of prior informed consent and mutually agreed terms to the access were observed.

From now, regarding the interface between the use of biodiversity and protection of intellectual property, this section is based upon a paper authored by Marcio Miranda Santos, a geneticist and chief-researcher of the National Center for Genetic Resources and Biotechnology (CENARGEN), and a very important stakeholder in the recent Brazilian process of access to genetic resources legislation. In this paper[18], he considers that any regulation and policy in the field of biotechnology and biodiversity should take into account two main sets of co-relations: (a) the contribution of the classic tools of intellectual property system to a protecting model for biological material and the needs for adapting it; and (b) the implication of the intellectual protection to the conservation and sustainable use of the biodiversity.

[18] SANTOS, Marcio Miranda, *Direitos de Propriedade Intelectual na Area Biologica*, in www.bdt.org.br

It is recognized that the arrival of biotechnology, associated to those new conditions of the world economy, has brought a huge challenge to the intellectual property rights systems. TRIPS, regional agreements and national regulations have already addressed this concern.

Besides the economic and market aspects cited above, politics, moral, ethics and religion pose many and profound topics of controversy regarding intellectual property over living organisms and biological processes. Even though, not hiding those formidable points as assigned before, this paper will concentrate technically in aspects of intellectual property mechanisms: their application to biotechnology and implications for the conservation and sustainable use of biodiversity.

4.1.1 Application of intellectual property to biological inventions

According to Article 27.1 of TRIPS, *"patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".* These requirements are met in all national regulations and bring specific difficulties in the field of biological material, mainly if we remember that besides these traditional requisites, the other required procedure for patenting is to disclose the invention.

4.1.1.1 Novelty and inventive application

It is broadly accepted that the requisites for novelty and inventive application are not easily applied to patenting procedures of biological products and processes. This has been a continued discussion in many countries, mainly in the United States and the European Union, and has been approached by new regulations and policies on the issue.

Prior to 1977, the United States Patent and Trade Office (USPTO) used to consider natural products and processes as “products of nature”, and thus non-patentable. Since this year, however, a judicial decision settled that patents could be asked for “new” forms or compositions of natural products. It maintained as non-patentable natural products “per se”, in the way they are found in nature. As a consequence of that decision, even extracted or purified natural products started to be considered “new” and therefore, possible to be patented.

Another important judicial decision was taken by the U.S. Supreme Court in 1980, in favor of patenting a genetically modified bacteria and establishing that engineered organisms could be patented as ""“manufactured” or “composition of matter”. This was the juridical milestone that allowed the USPTO to keep on giving patents on plants and animals, excluding human beings.

From the critics of patenting, it is said that biological innovations lack inventive activity, that they originate primarily from manipulation or combination of genetic material already existing, or, more defendable, the innovation is no other than just an isolation of organisms or substances that occur in nature. Saying that these achievements are discoveries and not innovations is the most common argument used against patenting biological products and processes. Nevertheless, even recognizing that gray area in the concept, the institutions that invest in the development of biotechnological products and processes see in a patent system the only way to grab their rights and to avoid an unauthorized use of their innovations, once they become known by the competitors.

4.1.1.2 Full disclosure

Biotech patents can be conceded for products, substances or organisms, uses and methods. While describing creation processes or use of biotechnological products can be, most of the time, possible, a full description of an organism or part of it is a serious problem for attending the patent requirement for disclosure.

In the case of micro-organisms, this problem was partially solved by the Treaty of Budapest that establishes an international system of deposits and proceedings regarding intellectual protection. The agreement characterizes some collections as “International Depositary Authorities (IDAs)”. Any deposit made in one of the IDAs and accepted by any of the member countries is taken as filling the requirements of their national regulation. In this way, the impossibility of describing a microorganism is overcome by the deposit in an IDA where it will be available for anyone interested in knowing it. The deposit also fixes another characteristic of the disclosure proceedings in this area. Very frequently, the possibility to repeat the process of obtaining an organism can not be assured by the written description, because of its own random changes, due to natural biological processes.

4.1.1.3 Industrial application

Any claim for patent must clearly specify the industrial use of the product or process to be protected. In biotechnology, not accomplishing the requisite can lead to extended privileges to experimental processes and impeding scientific and technological development. The misunderstandings about that concept can open a way to numerous applications in patent for gene sequences, therapies and biological processes in general, with no flavor of industrial use and causing trouble for the science and research in the respective areas.

As an example of that, in 1991, the U.S. National Institutes of Health (NIH) asked for patenting 2,421 different nucleotide sequence of the human genome. The claim was properly rejected by USPTO after a long procedure, in which the examiner argued about the issues of full disclosure, comprehensiveness, and obviousness. After that, NIH announced that would not apply for patents in gene sequences anymore. This position seems to be the current one of the Government of the United States, emphasized this year, after the completeness of the draft of the human genome sequencing.

Even though, those official declarations do not close the debate. The trends among the private companies are clearly to struggle for patents in this area. Explicitly, the companies even admitting not to apply for patenting the whole genome, would fight for patents of specific gene sequences, related to determined diseases. These sequences would allow them to develop test kits and treatments. With the new sequencers and automated methods of making homologies between genes and their functions, the race for patenting gene sequences is just beginning. New and crucial controversial issues will arise and will require a clear point from the policy making people.

4.1.2 Intellectual property rights and the conservation and sustainable use of biodiversity

4.1.2.1 Patents and access to biological resources

Generally, the biological diversity components are considered discoveries, and do not fulfill the requirement of inventiveness needed to be patentable. But in fact, in some countries, patents have been conceded for “technological innovations” related to a living form or its part, regardless if it is a microorganism, a plant, an animal (genetically modified or not), or a gene or sequence. Since they have a defined industrial use, they are considered new and have been fully described.

The basic questions in this scenario refer first to the possible restrictions that the patenting of biological products and processes can pose to the research institutions and, second, maybe more importantly, the fair and equitable sharing of benefits generated by the patent, since this protection refers to biological material and traditional related knowledge, and these components shall be otherwise protected.

There is a fear that extensive patent coverage to living forms would constitute a strong private appropriation of the genetic resources, restraining their eventual use in other applications of economic and social distinct interests. Particularly on plants, patenting raises much concern, since it is different from the protection through plant varieties protection, and would not allow the utilization of the protected plant to develop new ones.

The creation of plant varieties is essentially a step-by-step process based, most of the time, in former plants. The prohibition of using those protected seeds could bring negative consequences for the technological development in agriculture and for food security. In this particular, even under a system that would permit patents for plants, certain exceptions for research purposes should be granted.

Out of Brazil, patents have been conceded to genetically modified plants, like soybean, rice and potato, with the repercussions inferred above. In Brazil, some applications for patents in INPI relate to very broad biotechnological processes, which, unless clear and specific guidelines are provided, may cause obstacles to certain sectors of research[19].

Patenting of living forms and biotechnological processes represents a component of the strategy that aims to guarantee the entry and permanency of private companies in emerging markets, especially those companies associated with pharmaceuticals, biotechnology and new seeds for agriculture. This means: the investment and the modern biotechnology. Another component of that strategy is the biological diversity itself (natural resources). These are the parts of the equation. While the second one is found, mainly, in the tropical belt of the planet, formed basically by poor and developing countries, the first components (investments and technology) are located in the industrialized countries. The achievement of benefits (and its fair and

[19] It is quite difficult to determine at the time the application is filed what constitutes a "broad" patent. There is not a technical definition to propose which will tell a patent examiner which applications are "too broad". For many inventions, it is only later, as the particular field advances, that it is possible to determine which patents are broad and which are not

equitable distribution) originated from the use of biodiversity will be as big as the transfer of technology will settle, in the opposite direction.

4.1.2.2 Plant protection and diversity of genetic resources

Another source of concern regarding intellectual property over genetic resources relates the role of the development and crop of new varieties to the conservation of biological diversity. The homogeneity of the new plants (protected either by breeder's rights, patents or trade secrets, depending upon the legal system) has contributed to a substantial loss of genetic variability, especially of the major food crop cultures.

The decline of genetic variability in the level of traditional varieties and landraces has reached an enormous proportion. In India, 30,000 rice varieties were cultivated a few decades ago. Today, 75% of rice production of that country comes from approximately 30 varieties. In Sri Lanka, 2,000 rice plant varieties were raised in 1959. Today, there are only 5 varieties of rice being cultivated in that country.

Marcio Miranda Santos, in his paper, mentions Professor Donald N. Duvick, from Iowa State University who points out that the abandon of traditional crops in favor of modern varieties, fair broadly adapted, is the main cause of erosion of the genetic resources maintained *in situ* in centers of genetic diversity. Intellectual property tools will be used only in crops with potential profit-making by the selling of seeds. So, not all crops will be affected, but that effect can be very dangerous in the centers of genetic diversity, by undesired crossbreeding.

This stresses the need to stimulate the collecting activities for conservation in order to avoid the loss of extremely important parts of genetic diversity, particularly the landraces[20].

Strategies that aim to stimulate the innovations must promote decentralization, diversity, and participation in all levels. In this way, the existing intellectual property instruments must be adapted in this area to produce better results. These adaptive measures are supposed to act jointly in favor of conservation of biological diversity, the vital goal for humankind. And, to stress, in this adaptation process, the way is two fold: to be a tool in the sharing of benefits in order to allow countries to conserve biodiversity, and to protect the traditional rights related to biodiversity, which is also another conservation sound action.

Because all the reasons mentioned above, compiled from Marcio Miranda Santos's paper, the Convention on Biological Diversity[21] was signed in 1992 after a long and hard period of negotiations, and has been ratified by 178 countries.

The Convention provides a legal framework for a comprehensive ecosystem-based approach to conservation. It introduced the term **access** and its respective legal implications in three different contexts**: access to genetic resources**[22], **access to technology**[23], and **access to benefits derived from the use of biodiversity**.[24] In accordance with this treaty and the tasks required for its implementation, the Brazilian Congress and Government have been working since 1995 to formulate the

[20] For example, intellectual rights on plants and seeds could bear condition that holders dedicate some percentage of the income to conservation activities. This at least would provide a specific object to which such funds could be directed and turn the alleged negative of IPRs into a positive value

[21] Signed in Rio de Janeiro, at the United Nations Conference on Environment and Development (UNCED), in June 1992. It entered into force internationally as of December 29, 1993 and in Brazil as of May 1994. The permanent secretariat is located in Montreal. As of August 14th, 2000, 178 countries had ratified the convention, but not the United States.

[22] Article 15 – **Access to Genetic Resources**.

[23] Article 16 – **Access to and Transfer of Technology**.

[24] Article 19 – Handling of Biotechnology and Distribution and Distribution of its Benefits. (…) 2. Each Contracting Party shall take all practicable measures to promote and advance priority **access** on a fair and equitable basis by Contracting Parties, especially developing countries, **to the results and benefits arising from biotechnologies based upon genetic resources** provided by those Contracting Parties.

domestic legislation required to regulate the vector of the CBD dealing with access to genetic resources.

Introducing the three different concepts of access early on allows us to present, in very simplified terms, the relationship between them as envisioned in the CBD (albeit not explicitly). The conservation of biodiversity implies compensation for access to genetic resources via access to technology and to the benefits deriving from its utilization. This relationship does not consist solely of payment or transfer of technology, but must also consider yet another factor: the role of indigenous populations and local communities. The CBD, recognizing the indispensable contribution of the lifestyles of these groups to the conservation of biodiversity, determined that access to benefits should encompass a just and equitable distribution of rewards to those communities whose knowledge contributes to effective utilization of biodiversity, in order to stimulate the maintenance and reproduction of their cultural, social, and economic integrity.

This simplification hides the much larger judicial and political questions raised by the CBD and the formidable process of implementing this treaty.

Access to genetic resources, generally speaking, is understood to mean the use of genetic resources for scientific or commercial ends. Regulation of this activity aims to limit utilization to those instances in which it is environmentally sustainable. It also strives to ensure that access be properly administered in contractual terms; that the benefits – financial and technological – be equitably distributed; and that indigenous and local communities, whose practices are so important for the protection of biodiversity, receive adequate recognition and compensation for the utilization of their practices. In addition, legislation must recognize that such activities coincide with issues of intellectual and material property rights that are included in legislative and judicial regimes, established domestically but recognized internationally.

5 PROTECTION OF INDIGENOUS RIGHTS RELATED TO BIOLOGICAL DIVERSITY

One of the most important challenges for the lawyers and for the biodiversity regime builders, now and in the years to come, is to design and to enforce this new type of intellectual property rights.

As characterized by David Downes and Sarah Laird:

> *Much of the world's surviving biological diversity is found in areas inhabited by indigenous and local communities that are relatively impoverished and marginalized within both political and economic systems. Yet these communities typically have rich traditions of knowledge associated with their biodiversity and biological resources (together termed "bioresources"), as well as practices relating to those resources.*
>
> *Traditional knowledge is valuable in several ways. It informs resource management systems and practices of resource use that often have relatively low impacts upon bioresources. The existence of these systems and practices explains in part why these peoples are the custodians of much of the world's richest stores of biodiversity. Traditional knowledge also comprises extensive knowledge of the practical uses of these resources, as sources of medicines, foodstuffs, and other goods. As a result, traditional knowledge is itself a valuable resource not only for these communities but also for outsiders, including academic researchers, government agencies, and commercial firms, both foreign and domestic. Traditional knowledge has been used in many industries as a starting point for new product development, in sectors such as specialty food and beverage, pharmaceutical, agriculture, horticulture, and personal care and cosmetics. It remains an important resource for many commercial research and development programs.*
>
> *Traditional knowledge is also important to its holders as an integral part of their cultural heritage. As such, its protection for ensuring the enjoyment of the right to maintain and take part in cultural life recognized under international human rights instruments. Similarly, there is growing recognition that indigenous peoples have rights to control and protect this traditional knowledge as a form of intellectual property, as recognized in the UN Draft Declaration on Indigenous Rights. Because the structure and content of traditional knowledge is intimately linked with local bioresources and ecosystems themselves, the protection of rights to cultural heritage is closely*

linked to the protection of the environments and living resources of indigenous and local communities[25].

The objective of this chapter is to achieve a general, not conclusive summary, on the subject of the protection of the traditional knowledge in Brazil (and in a small sum in the world), based essentially on the bills of law under analysis in the Congress and on the Provisional Decree 2052 of June 2000 in order to organize itself as a subsidy, a fast reference at this current moment of normative definition of the subject.

5.1 The CBD's principles on the rights of indigenous and local communities

One of the significant advances of the Convention signed in 1992 was to recognize the strong relationship between biological diversity and cultural diversity. One can almost conclude that countries with rich cultural diversity are mega-biodiverse countries[26]. This means that one of the best ways to conserve biodiversity is to ensure fair conditions of living, reproduction and development to local and indigenous communities. This objective can be achieved through the guarantee of their integral rights, rights over their lands, natural resources and traditional knowledge.

The Convention affirms that countries have legal control over their biodiversity and a right to share the benefits from its use. It seeks to promote greater sharing of benefits and to assist developing countries. Some of them are the most biodiversity-rich yet they often lack resources and incentives needed for conservation.

[25] DOWNES, David and LAIRD, Sarah – Community Registries of Biodiversity-Related Knowledge, 1999
[26] POSEY, Darrel and DUTFIELD, Graham – *Indigenous Peoples and Sustainability: Cases and Actions*, IUCN and International Books, Utrecht, 1997.

The Convention also calls on governments to help indigenous and local communities protect their traditional knowledge and practices relating to biodiversity, and to establish incentives to encourage fair sharing of the benefits from those traditions[27].

The already classic three-fold objectives of the Convention on Biological Diversity are: conservation of the biological diversity, sustainable use of the biological diversity, and equitable distribution of the derived benefits of the use of the biological diversity.

Under this third point – equitable distribution - the CDB contemplates two compensatory mechanisms. First, the distribution of benefits between the nations that require and give access to genetic resources, regulated in Article 15 of the Convention (which deals with the sovereignty and the need of previous agreements between countries). And second, the distribution of the deriving benefits from the use of the indigenous and local communities' traditional knowledge associated with genetic resources, between the petitioners and the communities themselves.

This last point constituted the letter "j" of Article 8 of the Convention and, together with other numerous normative intentions (and actions) that started to appear in other international acts and internal legislation, fed this world-wide disseminated process of creation of a full legal mechanism for protection of the traditional knowledge. Since the beginning, this creation has represented a formidable task, provided that until today a paradigm on the subject does not exist. Besides that, the traditional knowledge itself characterizes by being absolutely unique and having uneven features that do not subject it to the typical codes of intellectual property.

[27] Article 8(j): Each Contracting Party shall, as far as possible and as appropriate: (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

Still in the context of the Convention, it is necessary to carry in mind that the institute of “previous informed consent”, widely defended today as one of the mechanisms to be adopted for the protection of the traditional knowledge, is not established in Article 8(j) or in any other part of the CBD. The previous informed consent in the Convention circumscribes to the relationship between nations. However, a pragmatic and theoretical evolution of the concept made it to transport, with much adequacy, to the protection of the indigenous knowledge and to any activity that involves collection of materials originated from traditional communities.

Thus, in Brazil, for example, the Resolution 196, of 1996, of the National Council of Health (Conselho Nacional de Saude) of the Ministry of Health, that deals with the regulation of bioethics in medical research, brings a chapter called “Free and Informed Consent”, which defines in detail the procedures for the previous consent of traditional communities involved in scientific inquiries.

Therefore, although still not consecrated in the text of the CBD itself, the principle of the previous informed consent of the traditional communities already stand as a firm and consensual one in the regime of biodiversity for this aspect and has been reflected in all national and regional regulations being created.

A last commentary that reports this subject to the Convention refers to the concept of “intangible component”. Originally, this conception was developed to characterize the proper nature of the material whose use was to discipline. That is, the contained genetic information in the biological material that, by its own nature has this intangible character. By a theoretical evolution, and crystallizing mainly in the scope of the Resolution of the Andean Community on Access the Genetic Resources, the concept was dislocated to characterize afterwards the traditional knowledge associated with a genetic resource. This concept appears explicitly with this dislocated meaning only in the cited Andean Resolution, but rhetorically it spreads around the world.

Reflecting that original definition of the concept, the Brazilian Government's bill of law (PL 4751/98) and the last June provisional decree (MP 2052/00) on access to genetic resources adopted the thesis, world-wide innovative, to define the good to be protected as the contained genetic information in the component of biodiversity. Until this moment, all the legislative proposals, including the two already under analysis in the National Congress, approached the protection of the genetic resources and their derivatives taken as a whole, as the physical material. This approach looks for an inclusive protection, to include the genetic information in itself as it protects the material as a whole. They are about two different strategies, but they have the same objective. The parameter for choice between one of them will be centered in the effectiveness it can achieve.

5.2 Legislative antecedents

Before approaching the legislative proposals themselves, one should bring to comment, some previous and parallel contributions that had also helped to conform the protection of indigenous rights.

At first, one should recall the congressional proceedings to approve the Patent Law. Until April of 1996, the Bill of Law 115/93 (afterwards transformed in the Patent Law) was in the Senate. Among the most controversial subjects of this bill the dimension and repercussions of living forms patenting used to appear in detach. In that long way the Bill had to go through debates and amendments in the Committees of Constitution and Justice, Economic Subjects and in the Plenary, the participation of Senator Marina Silva, of Acre State, was highlighted in the very end by the elaboration of two proposals of amendments on biotechnology patenting. The first one, adding an article in the chapter about who is entitled to hold patents, with the following text:

> *Local communities and indigenous populations whose traditional lifestyles contribute to the conservation and sustainable utilization of biological diversity will be assured of an equitable partition of patent rights related to the use of*

> *their knowledge, innovations, and practices as applied to local biological resources.*

A second one was for creating another condition for the patent claim, when related to the knowledge of an indigenous or local community, adding the following paragraph to art. 24 of that bill of law:

> *In the case of patent claims related to the knowledge, innovations, and practices of local communities and indigenous peoples as applied to biological resources, the request must include documentation indicating the precise geographic and ethnological origin of the biological material and/or of the biotechnological process, and certifying the existence of a contract with local communities and indigenous populations designed to ensure the equitable partition of patent rights.*

These two simple legal rules were a vigorous attempt to protect the traditional knowledge. The first one determines the equitable distribution of benefits in case of patent related to a traditional knowledge. The second creates the so-called "passport" of the biological material object of the patent, the most effective condition for a sharing of the benefits. The amendments were rejected, but they were also the seed for the following initiative of Senator Marina Silva to begin the process around a more comprehensive proposal about access to genetic resources.

The second Brazilian legislative antecedent to be brought is the Bill of Law 2057/91, known as Statute of the Indigenous Societies, which carries three chapters applied to this issue: one on intellectual property rights, a second on non-patentable intellectual property, and a third one on copyright. The first ensures indigenous communities the right to obtain patents. These patents would be granted collectively and would be shared with other communities that withhold the same knowledge. The second chapter creates a *sui generis* protection for non-patentable knowledge, also with a collective coverage, and whose use will be allowed only after a monetary payment. The third one deals with widely known institute of copyright, in order to protect the authorship of the indigenous communities over their cultural and artistic manifestations.

Even though this is not the objective of this study, we are forced to conclude that reciprocal adaptations will be needed to the law of access to genetic resources (in its chapter on protection of the traditional knowledge), and to the bill of law of the indigenous societies, in the above mentioned chapters, in order of getting an effective and harmonious system on protection of indigenous knowledge rights.

5.3 Legislative proposals in Brazil

In this section we present a comparative table of the main differences between the three bills of law and the Provisional Decree 2052/2000 under examination of the National Congress. The picture is self-clarifying, not being necessary to repeat in the text its conclusions. Perhaps one should only add some considerations about the political moment of the introduction and discussion of those bills. The Senate's bill, authored by Senator Marina Silva (with a substitutive by Senator Osmar Dias), was approved by the Federal Senate in November of 1998. In this same year, in June, the Representative Jaques Wagner introduced in the House of Representatives a bill of law on access to genetic resources, almost identical to the Senate's bill. This piece had basically the objectives of speeding up the political process in that House and introducing modifications suggested by some non-governmental organizations, which were not accepted in the substitutive of Senator Osmar Dias. These alterations were related to the property of the genetic resources and to the role of the indigenous communities in the concession of the access.

Also in 1998, in August, the Executive finally presented its bill, after a few years of closed discussions inside the Inter-ministerial Group of Access to Genetic Resources. The main difference of the governmental proposal resides in the following aspects: its radical approach when proposes to amend the Constitution considering the genetic patrimony as a good owned by the country; the simplification of the concession process; and the restriction of the indigenous and traditional communities' rights.

The three bills[28] are in the House of Representatives, where a special commission was created to analyze them jointly. Also, another special commission was appointed to discuss the proposal of amendment to the Constitution mentioned above. However, in June of 2000, pressed by scathing criticism about serious problems caused by the lack of specific legislation on access to genetic resources, Government issued the Provisional Decree 2052 (which in Brazil legal system has the force of a law), establishing the Brazilian regime of access to genetic resources. Basically, it repeats the Government 1998 bill, with some and crucial modifications, mainly in the chapter about the protection of indigenous rights, providing slightly more protection.

It seems, currently, that all the discussions and seminars organized around the bills will be forgotten before the new and effective Provisional Decree, since it is already a law. Pragmatically the Congress meetings will be held on discussing the Decree and not the previous bills. In any case, since the Provisional Decree has to be discussed and approved in the Congress, and the Congress already gets other previous and comprehensive texts, surely this study here about them may have its usefulness.

Given the importance of the theme, it should be added here that besides this chapter on indigenous rights the most controversial debate would be on the question of sovereignty and property of the genetic resources. Specifically on the question of the property of the genetic resources, keeping in mind that the Senate's and the Government's bills bear the same idea (to consider the genetic resources as public goods), it would be useful to bring to light the Cláudio Pacheco's lesson on domain of the public goods:

> *"… [The] public domain moves away and distinguishes itself from the institute of the civil property, losing many of its features of use, enjoyment and availability of such goods. The public entity, entitled in this domain, will not*

[28] There is a fourth bill, by Representative Silas Camara, but this repeats mostly the Government's bill.

have then a direct use, or a proper enjoyment, or free availability, or an attribute of exclusiveness in the exercise of its right. … [The] public domain is mere presumption, it is not a true domain, and can only be valid as a clause of exclusion of the entire domain, either public, or private. … Truly and legitimately examined, the people's common use is incompatible with any concrete or effective conception of domain. The right that the public entity can exert on such things will be to legislate or to regulate, to command that common use joint, or to exert the police power in order to achieve the direction of a good order of the common use. In summary, that public competence that does not submit itself to a narrow notion of domain."

In order to get a complete apprehension of which each one of the bills and the provisional decree's texts says in the specific field of protection of indigenous knowledge we organized the following comparative table that allows us to view quite accurately the main divergences among the proposals.

Comparative table of the main aspects of the bills and of Provisional Decree 2052/2000

Aspects / Bills	**Senate's bill** **PLS 306/95**	**House's bill** **PL 4.579/98**	**Government's bill** **PL 4.751/98**	**Provisional Decree** **MP 2052/2000**
Coverage of the concept of access to genetic resource	Wide, including derived products, semi-domesticated crops and traditional knowledge (art. 1º)	Wide, including derived products, semi-domesticated crops and traditional knowledge (art. 1º)	Refers to the genetic information itself and to the associated traditional knowledge (art. 1º)	Refers to the genetic information itself and to the associated traditional knowledge (art. 1º)
Concept of the titular of the traditional knowledge right	Indigenous population and local community (various articles and definition)	Indigenous community and traditional or local population (various articles and in the concept: indigenous society)	Indigenous and local communities (without definition of indigenous community)	Indigenous and local communities (without definition of indigenous community)
Possibility of separation of the material resource from the traditional knowledge	Yes	Yes	Yes	Yes
Regime of ownership of the genetic resources	Public good for special use of the nation (art. 2º)	Good of public interest (art. 2º)	Public good, (art. 2º and parallel amendment to the Constitution)	Public good, (art. 2º and parallel amendment to the Constitution)

Prior informed consent principle	Yes (art. 5º, III)	Yes (art. 5º, III)	Yes, but not complete	Yes
Who is charge to detail the proceedings to prior informed consent	The competent authority (art. 43, parágrafo único)	Without specification, presuming to be the community (art. 45, parágrafo único)	Without reference	Without reference
Duration and characteristics	Unprescritible and unalienable (art. 5º, V)	Unprescritible and unalienable (art. 5º, V)	Without reference	Without reference
Access to human genetic resources	The law does not apply. Delegates to Executive, temporarily, the competence to regulate, subject also to personal prior informed consent (art. 8º, I)	The law does not apply. Delegates to Executive, temporarily, the competence to regulate, subject also to personal prior informed consent (art. 8º, I)	The law does not apply, without any other provision (art. 4º)	The law does not apply, without any other provision (art. 3º)
Exchange of genetic resources between the traditional communities	The law does not apply (it continues free – art. 8º, II)	The law does not apply (it continues free – art. 8º, II)	The law does not apply (it continues free – art. 5º)	The law does not apply (it continues free – art. 4º)
Entry in indigenous lands	It depends on authorization of competent authority and prior informed consent of the community (art. 17, § 3º)	It depends on authorization of competent authority and prior informed consent of the community (art. 17, § 3º)	Authorization of the Indian office, after hearing the indigenous community (art. 9º, § 4º)	Authorization of the indigenous community, after hearing the indian office (art. 13, § 7º)
Participation of the community in the contracts on access to genetic resources (material)	Part in the previous related contract (contrato conexo prévio) (art. 28, a)	Part in the previous related contract (contrato conexo prévio) (art. 28, a)	Co-part at the same side of the government, being represented by the official indian authority – FUNAI (art. 16)	Co-part at the same side of the government, (arts. 11, I and 25, I)
Participation of the community in the contracts on traditional knowledge	Part in the main tri-partite contract (art. 19, c)	Part in the main tri-partite contract (art. 19, c)	Executive branch is authorized to concede the access to knowledge and its transfer (art. 8º, I e III)	Executive branch is authorized to concede the access to knowledge and its transfer, after hearing the community (art. 11, II and IV)
Compensation for the community in the contracts on access to genetic resources (material)	Fair and equitable participation in the benefits, indicated in each contract (art. 28, par. Único)	Fair and equitable participation in the benefits, indicated in each contract (art. 28, par. Único)	Percentage in the benefits from the economic exploration (art. 11, § 1º)	Percentage in the benefits from the economic exploration (art. 21, § 1º)

Compensation for the community in the contracts on traditional knowledge	Monetary, goods, services, intellectual property, among others (art. 44)	Monetary, goods, services, intellectual property, among others (art. 44)	Percentage in the benefits from the economic exploration (art. 11, § 2º)	Percentage in the benefits from the economic exploration (art. 22)
Remuneration through a trust-fund	Without reference	Without reference	Without reference	Without reference
Personal condition for recognition of the knowledge	Without reference	Without reference	Without reference	The knowledge is recognized for the community if only one member of the community get it
Legitimacy for the defense of traditional knowledge rights	Public attorney (art. 44, § 1º)	Public attorney and other juridical persons related and the communities themselves (art. 44, § 1º)	Without reference	Without reference
Register	It creates the non-bind and non-compulsory register (art. 44, §§ 2º a 5º)	It creates the non-bind and non-compulsory register (art. 44, §§ 2º a 5º)	It creates a data base (art. 8º, VII e VII), without specify objectives	It creates a possible register (art. 8º, paragraph 3º), without specify objectives
Role of the communities in the extra-contract authorization for access to their knowledge and to genetic resources in their areas	They can ask the competent authority that do not authorize the access to the resource (art. 46, sole paragraph)	They can deny the access to the resource and to the knowledge (art. 46, sole paragraph)	Without reference	They can require the indication of origin in publications and explorations and impede non-authorized people to use the knowledge (art. 9º, I, II and III)
Intellectual property over products and processes related to genetic resources and associated traditional knowledge found in Brazil	Prohibition of patenting of products related to traditional knowledge if the access had not been made in conformity with the law (art. 47)	Prohibition of patenting of products related to traditional knowledge if the access had not been made in conformity with the law (art. 47)	Without direct reference, only imposes the accomplishment of the law as a requirement for the concession of patent based in a genetic resource associated to a traditional knowledge (art. 20)	Without direct reference, only imposes the accomplishment of the law as a requirement for the concession of patent based in a genetic resource associated to a traditional knowledge (art. 28) and a provision that the indigenous rights will not prejudice other IPRs (art. 8º, paragraph 4º)
Intellectual property over products and processes related to genetic resources and	Requirement of demonstration that the access was regular and according to a previous informed consent (art. 41, sole paragraph)	Requirement of demonstration that the access was regular and according to a previous informed consent (art. 41, sole paragraph)	Without reference	Without reference

associated traditional knowledge from abroad				
Existing use of the knowledge	Without reference	Without reference	Without reference	Legalized to the good faith users prior to June 30th, 2000

5.4 Discussion on a system of protection of the traditional knowledge

This consideration brings us ethical and legal issues relating IPRs and the use of indigenous knowledge. On this regard one can identify two major trends. The first states that is not necessary to design new institutes of IPRs to regulate the indigenous rights. It is accepted that the existing instruments are sufficient to protect the traditional knowledge. Basically, it is agreed that trade secrets could be an effective tool for the contracts between the companies and the communities. The characteristic of a trade secret is its flexibility and permanence. Also, it does not require an inventor and a date of creation. Some attempts have been made in this way. In Peru, a few years ago, agreements based in these principles were negotiated between indigenous tribes and a bioprospecting initiative[29].

The second and stronger trend in this field realizes that the very inner characteristics of the traditional knowledge and for its better contribution to biodiversity conservation goals, a new and *sui generis* intellectual property system for this kind of knowledge should be built and implemented.

Although it is generically suggested that the discussion on a *sui generis* system of protection of traditional knowledge and on intellectual property are reciprocally exclusive, mainly among the most radical trends, based, for example,in the thought of Vandana Shiva, one could accept, in contrast, that an approach that incorporates the two dimensions is necessary and, more than that, is even more adjusted. The *sui-generis* system for indigenous rights would act internally in the role of

[29] TOBIN, Brendan – *Protecting Collective Property Rights in Peru – The Search for an Interim Solution*, 1997

recognizing and protecting the traditional communities' rights. On the other hand, establishing some key understandings on intellectual property, perhaps under the form of a treaty, would serve to limit the possibilities of unauthorized use of the traditional knowledge for patents in the import countries. Without such agreement national regulations would have little effectiveness.

Therefore, for increased effectiveness in all levels, a comprehensive regime of protection of the traditional knowledge would have to be structured by two regulations, (a) a national law of *sui generis* protection, and (b) a multilateral agreement to make the use of the traditional knowledge dependent on demonstration of previous informed consent (it could be a protocol to the Convention on Biological Diversity).

5.4.1 National legislation

An expressive part of the desirable points of a national legislation for protection of traditional knowledge can already be detected in the proposals in progress, as well as in diverse foreign proposals, independently of the point of view that one wants to adopt. However, other points can and must be enclosed from a more systematic analysis of the subject. Before deciding about a regulatory approach, public agents and civil society would have to reflect on all these questions and clearly choose a way. In a broad sense, we consider that these questions could be, schematically and not conclusively, organized in the following points:

a) What to protect the traditional knowledge for?
    - To sell it as an ordinary good and to assure maximum private benefits?
    - Because it is important for the conservation of biodiversity?
    - To preserve the communities and their culture?

b) Which is to be protected? Which is the nature of this good?
    - The knowledge itself?

- The associated genetic resource?
- How to characterize the collective nature of the knowledge?
- Should be accepted intellectual property on this knowledge?

c) Which would be the regime of ownership of the genetic material associated to a traditional knowledge?
   - Public good?
   - Private good?
   - Public good of special use?

d) Who should be in charge of protecting traditional knowledge?
   - The Government?
   - The community?
   - Which is the role of the civil society and the Public attorney?

e) Which should be the form of compensation?
   - Monetary?
   - Non-monetary?
   - How to conciliate the payment with the collective nature of the knowledge?

The discussion about these points, together with the observation of the experiences already carried out could lead us ahead to accept, preliminarily, the systematization made for Brendan Tobin for a regime of protection of traditional knowledge. According to Tobin, a lawyer who worked in the negotiations between a bioprospecting initiative and indigenous peoples in Peru, such regime should:

a) Recognize that the rights of the communities come from the development of its knowledge itself, and not of any act of the government;
b) Assure the recognition of the collective nature of the knowledge, as much inside as inter-generations of indigenous populations;

c) Assure that the control of the use of the knowledge remains firmly in the hands of the indigenous populations, even when such information is in the public domain;
d) Assure that the right of any community or indigenous people do not infringe the right of other communities or peoples to use and manage this knowledge or the resources;
e) Prevent the creation of monopolistic rights on the knowledge and prevent the possibility of acquisition of monopolistic rights on the knowledge or on the associated biological resources;
f) Assure the equitable distribution of the benefits among the communities;
g) Assist the valuing of the traditional knowledge, promote the traditional uses and minimize the impacts in the biological resources and in their cultures;
h) When it is established that the genetic resources are patrimony of the nation, to make a clear distinction between the rights of the government over the resources from the collective rights of the communities over the knowledge;
i) Establish a presumption that the use of resources to which the knowledge is associated, in particular the related to medicinal plants, implies the use of that knowledge; and
j) Establish a register for the traditional knowledge.

Jointly with that question guideline mentioned above, this set of recommendations could satisfactorily consist in the embryo of a regime of protection of the traditional knowledge. They could play the pioneering role of regulating the interests of the indigenous and local communities, without abandoning the objectives of conservation of biodiversity and respect the interests of the country.

5.4.2 International agreement

Under this title, we would like only to register a brief consideration provided that this subject is in a very incipient step in the international arena. The most important premise is that hardly effectiveness in protection of traditional knowledge will be

obtained (as well as of the proper genetic patrimony), if it is regulated only the internal level. As well as in other items of the global agenda, the international normative counterpart becomes essential, under the risk of the achievements that would have been kept by the national law become completely ineffective.

This international perspective must contemplate two mechanisms basically: first, it must assure that any scientific or commercial use of the traditional knowledge is preceded by the previous informed consent, and is done in accordance with the national pertinent legislation. Secondly, an international mechanism that is to be discussed and implemented is the inversion of the principle of proof. If the proof of the guarantee of the previous consent will not be in charge of the demanded country, normally the richer and more endowed with financial and technological resources country, hardly the judicial protection will keep real effectiveness.

5.4.3 Some proposals and theoretical reflections

This section presents a very brief recollection of some legal and doctrinal approaches on the subject, possibly already outdated in some aspects, for what I beg the comprehension of the cited authors. However, I am sure that it still propitiates some elements for discussion and reference, which is the main objective of this text, as pointed out since the beginning. The contributions listed here, normative or theoretical, are simply compiled, without addition of critical commentaries in this article. Some are presented as topic items, since, in my opinion, they sound auto-clarifying, do not needing more details or explanation at this level.

5.4.3.1 Peru

a) Constitution:

- Lands owned by the indigenous peoples, without restraint on alienation clause.
- Art. 66: Renewable and non-renewable natural resources are patrimony of the nation. The State is sovereign in its exploration. A specific law establishes the conditions of their use and their concession to particular. The concession grants to the bearer a right *in rem*, subject to that law.

b) Proposal of a "Special Regime for Protection of the Indigenous Peoples Knowledge".

Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual (Indecopi) has been drafting a very complete[30] new intellectual property

[30] These following are the main articles of the proposal:

- **Reconocimiento de derechos Reconocimiento de derechos**

Artículo 1 - El Estado Peruano reconoce y valora el derecho y la facultad para decidir de las poblaciones indígenas, sobre sus conocimientos colectivos asociados a los recursos biológicos.

- **Uso y aprovechamiento de recursos biológicos y genéticos**

Artículo 4 - El uso y aprovechamiento de los **recursos biológicos y genéticos asociados al conocimiento colectivo** de las poblaciones indígenas se rigen por la legislación vigente en la materia.

- **Condiciones para el acceso a los conocimientos colectivos**

Artículo 7 - Quienes pretendan acceder a los conocimientos con fines de aplicación científica, comercial e industrial deberán solicitar a la población o poblaciones indígenas que hayan desarrollado el conocimiento colectivo en cuestión su **consentimiento informado previo y prever condiciones para una adecuada retribución por dicho acceso** y para garantizar una distribución equitativa de los beneficios derivados del mismo. Para tales efectos, deberán solicitar una **licencia de uso**.

- **Naturaleza colectiva de los conocimientos**

Artículo 10 - Los conocimientos protegidos bajo este régimen son aquéllos que **pertenecen a una población indígena y no a individuos determinados** que formen parte de dicha población indígena. **Pueden pertenecer a varias poblaciones indígenas.**

- **Inalienabilidad e imprescriptibilidad de los derechos**

Artículo 12 - Los derechos de las poblaciones indígenas sobre sus conocimientos son **inalienables e imprescriptibles**.

- **Conocimientos colectivos que están en el dominio público**

Artículo 13 - En caso que se trate de un conocimiento colectivo desarrollado por poblaciones indígenas, **que se encuentra en el dominio público**, se destinará el 2% del margen bruto de ganancia resultante de la utilización comercial o industrial de dicho conocimiento colectivo, así como de la comercialización de los productos desarrollados a partir de éste, al Fondo Fiduciario a que se refieren los artículos 52 y siguientes.

- **Objeto del Registro de conocimientos colectivos**

Artículo 16 - El **registro de conocimientos colectivos** de poblaciones indígenas tiene por objeto:

a) preservar los conocimientos colectivos de las poblaciones indígenas;
b) identificar los conocimientos que han desarrollado las poblaciones indígenas;
c) informar a las poblaciones indígenas sobre los contratos de licencia de uso que incluyan sus conocimientos colectivos.

- **Carácter confidencial del Registro**

regulation to give commercial value to traditional knowledge. The proposal was submitted for public debate in 1999, and currently Indecopi, has already finished the legislative proposal to create a Regime for the Protection of Collective Knowledge of Indigenous Peoples and a Regime on Access to Genetic Resources.

Both proposals grant intellectual value to the knowledge of thousands of communities existing in the country and to genetic resources, thereby creating the possibility to secure economic benefits from the commercial use of these resources.

One of the objectives of this project is the creation of new intellectual property rights (IPR) in the framework of international treaties to which Peru is committed. Through these new rights, the traditional knowledge of thousands of indigenous peoples will be registered and therefore can be recognized whenever it is used commercially by researchers or pharmaceutical laboratories, be they national or foreign.

Additionally, the creation of this new IPR registry will allow not only specifically entitled groups to benefit from the commercial use of their traditional knowledge, but all communities. For this, the document proposes the establishment of an

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Artículo 20 - El Registro de conocimientos colectivos de poblaciones indígenas **no podrá ser consultado por terceros**. Sólo tendrán acceso al registro de un conocimiento quienes cuenten con el consentimiento escrito de la población indígena titular de dicho registro.

- **Obligatoriedad de forma escrita de contratos de licencia**

Artículo 22.- La población o poblaciones indígenas que han desarrollado un conocimiento colectivo podrán **otorgar a terceras personas licencias de uso de dicho conocimiento** sólo mediante contrato escrito.

- **Conocimientos colectivos sobre recursos biológicos peruanos**

Artículo 25 - En caso se solicite el registro de un contrato de licencia de un **conocimiento que versa sobre un recurso biológico** cuyo país de origen sea el Perú, **el solicitante estará obligado a presentar una copia de la autorización de acceso** o la justificación respectiva, como requisito previo para la inscripción de la licencia.

- **No exclusividad de las licencias de uso**

Artículo 28 - Los conocimientos colectivos de las poblaciones indígenas **sólo pueden ser objeto de una licencia no exclusiva de uso**. En tal sentido, la licencia de uso de conocimiento colectivo de una población indígena no impedirá a otras utilizarlo ni otorgar licencias sobre este mismo conocimiento ni afectará el derecho de las generaciones presentes y futuras de seguir utilizando y desarrollando los conocimientos.

- **Derecho de las poblaciones indígenas de impedir el uso de sus conocimientos**

Artículo 30 - Las poblaciones indígenas, por el solo hecho de haberlos desarrollado, **tienen el derecho de impedir el uso por parte de terceros de sus conocimientos colectivos**, si es que éste se realiza sin su consentimiento informado previo.

- **Objeto del Fondo**

Indigenous Peoples' Development Fund (FONDEPI).

The Fund will be administered by the communities themselves under the supervision of Indecopi and will support the development of indigenous peoples by financing projects. A percentage of all sales resulting from the commercial use of traditional knowledge will go the Fund.

Access to genetic information will be regulated through an administrative procedure. The objective is to give the State a fair share of the benefits derived from access to these resources, which are the heritage of the State.

The project proposes the creation of a National Committee on Genetic Resources (CONARGE) as competent authority to grant access to genetic resources and to sanction illegal activities in this respect.

The document also proposes the creation of a Genetic Resources Conservation and Development Fund (FONDEREG) which shall promote the conservation and commercial use of these resources, within the established legal framework.

5.4.3.2 Philippines

Bioprospecting activities in indigenous peoples areas will only be allowed after the previous informed consent, gotten in accordance with the customary rules of the communities.

5.4.3.3 Costa Rica

Law of Biodiversity (April of 1998):

Artículo 52 - Créase un Fondo Fiduciario con el objeto de contribuir a la protección, preservación y desarrollo de los conocimientos colectivos de las poblaciones indígenas a través del financiamiento de proyectos y otras actividades orientadas a lograr los objetivos antes mencionados.

- Exclusion of the application of the law to exchange of genetic material and associated knowledge resultant of the practices, uses and customs of the indigenous and local communities without lucrative objectives.
- Previous informed consent of the indigenous peoples authorities.
- It is recognized the right to cultural objection, as the right of the local and indigenous communities to oppose to the access to their resources and the associated knowledge, by cultural, spirituals, social, economic, or of another nature reasons.
- The forms of protection of the intellectual property can be patents, trade secrets *sui generis* collective rights, and breeder's rights. Inventions derived essentially from knowledge associated to biological traditional practices or cultural practices in public domain cannot be protected.
- The Government recognizes and protects explicitly, under the name of *sui generis* communal intellectual property rights, the practices and innovations of the indigenous and local communities, related to biodiversity. This right exists and it is recognized in the law just for the existence of the cultural practice or knowledge. It does not require previous declaration, express recognition or official register.
- It creates a voluntary register of the communal intellectual property rights.
- It shall be defined a democratic process with the indigenous peoples and peasant communities to determine the nature, the reach and the requirements of these rights for its definitive regulation.

5.4.3.4 Africa (draft under discussion in some countries of that continent)

- The Government must recognize and protect the rights of the local communities.
- Previous informed consent.
- Local communities have the right to authorize the access.

- The Government must guarantee that 50% of the benefits gotten for any commercial use of the traditional knowledge must be transferred to communities.
- It must be established democratic mechanism for the definition of the rights and their exercise and protection.

5.4.3.5 Bioprospecting contracts

There are many contracts of bioprospecting in course nowadays in all the continents and with different actors. This paper presents just a sample of them, to show how the major institutions work on this field. It seems that the examples below get the characteristics that this kind of agreement should pose regarding protection of indigenous rights involved.

a) International Cooperative Biodiversity Groups (ICBG)

a.1) Types of benefits:

- Royalties – percentage of the commercial profits.
- Advance monetary payments – payments on pre-fixed dates.
- Equipment, training and infrastructure.
- Priority for research on illnesses that occur in the region.

a.2) Who should receive the benefits?

- Individuals and communities.
- Governmental institutions.
- Non-governmental organizations.

a.3) Procedures:

- Informed consent and consensus building.
- Independent legal and commercial advising during the negotiation.
- Know-how licenses.
- Material Transfer Agreement.
- Payment through a trust-fund.

b) National Cancer Institute (USA)

The National Cancer Institute - NCI, of the United States, in its bioprospecting activities, works, since 1995, with the Memorandum of Understanding. The main innovations of this type of agreement are: (1) all the collection work must be submitted to the supervision and organization of the supplying country; (2) the supplying country can claim the exclusive ownership of some derived substance from collected material; (3) the supplying country can negotiate directly with potential licensees (for example, pharmaceutical companies); and (4) it is necessary the authorization of the supplying country for any transference of material originated from this country from NCI to a third country.

Despite other limitations through internal United States regulation, the Memorandums of Understanding seem to show the broadest rules on sharing of benefits. These rules can be summarized in the following points:

- Monetary benefits must be negotiated directly between the native country and the possible licensee of a patented product.
- Joint patents are stimulated for all inventions developed jointly.
- If possible, first screenings and fractionating are carried out in the native country with training of staff and supply of material provided by the institution.
- The results of advanced screenings carried out in NCI will have to be repatriated for the native country in 90 days.
- The licensee must replenish in the native country or provide a monetary compensation.
- Distribution of material by NCI to a third country is subject to a previous informed consent of the native country.
- Publication must be arranged through an agreement with the native country.

These are not, obviously, provisions directed to the protection of the traditional knowledge, however these rules by analogy are applied to the relationship with the local communities and indigenous populations.

5.4.3.6 Some authors

Gurdial Singh Nijar, one of the major influences in the debate on a *sui generis*, regime proposes a register of the collective property that would qualify the indigenous peoples to register their knowledge and to use such register to control its commercial use. It considers that this right is non-monopolistic.

Darrel Posey focuses on the network of existing rights, related to the recognition and protection of what he calls “traditional resources”. His proposal, however, does not foresee a format for a protection system, only identifies regimes of protection, which, approached as a set of rights, would provide the recognition and the protection of the indigenous rights.

Graham Duttfield creates the concept of “traditional ecological knowledge” – a body of knowledge elaborated by a group or people, through generations living in contact with the nature. It includes a system of sorting, a set of empirical observations on the local environment and a system of auto-government on the use of the resources. Therefore, traditional knowledge does not mean “old” knowledge, anachronistic.

Property, including intellectual property, is not a strange concept to traditional and indigenous societies; however, patents and other classic instruments of intellectual property are fully inadequate to the protection of the traditional knowledge. Even the concept of “public domain” can be harmful to the indigenous communities, because it would favor exactly the use of the knowledge for major private companies.

For a criticism of the public domain, it can be affirmed that: a) not all traditional ecological knowledge is in the public domain; b) not consented allocation of the

knowledge in the public domain does not extinguish the legitimate title of the communities on its knowledge; and c) the holders of the traditional knowledge must be compensated by the maintenance of the knowledge and biodiversity.

4 BIBLIOGRAPHIC SOURCES

ALIFAR – Associacao Latino Americana da Industria Farmaceutica
"Declaracao de Guaruja", May 27th, 1999,
in http://www.alanac.org.br/noticiadeclaracaodeguaruja.htm.

ARCANJO, Francisco Eugenio Machado
"Como e Por Que Proteger os Conhecimentos Tradicionais Associados aos Recursos Geneticos" Presentation at Fiocruz course on intellectual property, October 1999, not published.

ARCANJO, Francisco Eugenio Machado
"Convention on Biological Diversity and Brazil's bioprospecting Bill: Sovereignty and ownership of genetic resources", in Revista de Direito Ambiental, 1998.

BARBOSA, Denis Borges
"The Brazilian Patent Law", in http://www.nbb.com.br/public/memos5.htm.

BELL, Janet
"Biopiracy's Latest Disguises", in Seedling, June 1997, Vol. 14, N. 2, pp. 2-19.

CIEL – Center for International Environmental Law
"The 1999 WTO Review of Life Patenting Under TRIPS – Revised Discussion Paper – November 1998", in www.ciel.org.

CIEL – Center for International Environmental Law
"Biodiversity and Wildlife Program", in http://www.ciel.org/bwp.html.

CORREA, Carlos
"Implementing TRIPS in Developing Countries",
in http://cecae.usp.br/tecla/html/uk/html/uk_pg_prop1.html.

DOWNES, David R. and LAIRD, Sarah A.
"Community Registries of Biodiversity-Related Knowledge – The Role of Intellectual Property in Managing Access and Benefit", prepared for UNCTAD Biotrade Initiative, in www.ciel.org.

EISENBERG, Rebecca S.
"Genes, Patents, and Product Development", in Science, vol. 257, 1992, pp. 903-908.

FONSECA, Antonio
"Concorrencia e Propriedade Intelectual", in Revista da ABPI, vol. 36, set/out 1998, pp. 3-24.

GONTIJO, Cicero I. F. et al.
"Sistema de Patentes", in Carta, vol. 10, 1994, pp. 127-145.

MASKUS, Keith E.
Intellectual Property Rights in the Global Economy, Institute for International Economics, 2000

POSEY, Darrel and DUTFIELD, Graham
Indigenous Peoples and Sustainability: Cases and Actions, IUCN and International Books, Utrecht, 1997.

PRIMO BRAGA, Carlos A.
"Trade-Related Intellectual Property Issues: The Uruguay Round Agreement and Its Economic Implications". 1995.

TEN KATE, Kerry and WELLS, Adrian
"The access and benefit-sharing policies of the United States National Cancer Institute: a comparative account of the discovery and development of the drugs Calanolide and Topotecan" Benefit-sharing case study, submitted to the Secretariat of the Convention of Biological Diversity, 1998.

SANTOS, Marcio Miranda
"Direitos de Propriedade Intelectual na Area Biologica", in www.bdt.org.br.

SHERWOOD, Robert
"Human Creativity for Economic Development: Patents Propel Technology", in Akron Law Review, Vol. 33, No. 3, 2000, pp. 351-363.

SHERWOOD, Robert
"Patent Disclosure and the Protection of Undisclosed Information: A Useful Dichotomy That Propels Technology", Presentation at Associacao Brasileira de Propriedade Intelectual (ABPI) Seminar, August 2000, not published.

SHERWOOD, Robert
"Compulsory Licensing Under TRIPS Agreement", in Latin American Law and Business Report, Vol. 3, Number 1, January 31, 1995, pp. 25-29.

SHERWOOD, Robert, SCARTEZINI, Vanda and SIEMSEN, Peter Dirk
"Promotion of Inventiveness in Developing Countries Through a More Advanced Patent Administration", in IDEA – The Journal of Law and Technology, Vol. 39, No. 4, 1999, pp. 473-506.

STAL, Eva and SOUZA NETO, Adeodato de
"Propriedade Intelectual: as Politicas de Patentes das Universidades, in http://cecae.usp.br/tecla/html/uk/html/uk_pg_prop1.html.

SUGUIEDA, Marcio Heidi
"Regulamentacao da Propriedade Intelectual no Brasil: Situacao Atual e Tendencias", presentation at III Encontro de Propriedade Intelectual e Comercializacao de Tecnologia, Rio de Janeiro, July 25th, 2000

TOBIN, Brendan
Protecting Collective Property Rights in Peru – The Search for an Interim Solution, 1997