Intellectual Property and Biodiversity

INTELLECTUAL PROPERTY IN THE WORLD TRADE ORGANIZATION AND ITS RELATIONSHIP WITH THE CONVENTION ON BIOLOGICAL DIVERSITY

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The relationship between intellectual property rights (IPR) and biodiversity may be the most controversial issue in the international environmental debate. The debate covers issues of great importance such as whether living matter should be patented, the relationship between IPR and the protection of traditional knowledge, innovations and practices, and with technology transfer. All of these topics are closely related with the Convention on Biological Diversity (CBD). The revision of the agreement on Trade Related Intellectual Property Rights (TRIPS) within the World Trade Organization (WTO), in the Millenium Round has increased the debate, because it may strongly affect the relation between IPR and biodiversity. These issues are also been discussed in other international forums. Such is the case of the meetings on traditional knowledge within the CBD, and the revision of Andean Decision 344 on a common industrial property regime within the Community of Andean Nations (CAN).

IPR where created and designed to promote technological development, mainly in industrial activities. Nowadays, with the evolution of new technologies, and particularly of modern biotechnology, IPR are been used for purposes that go far beyond their initial scope. New needs for protection of creations of the human mind, have required in the past adjustments of the IPR system. Likewise, nowadays an analysis to identify the positive and negative aspects of the application of IPR in this context is required, to be able to propose reforms to the IPR system or viable alternatives.

Discussions about issues such as whether living matter as existing in nature should be patented, are generally very emotive, due to their relation with ethical, sovereignty and property issues. Likewise, debates on protection of traditional knowledge directly affect the cultural integrity of ethnic minorities. On the other hand, there are important economic interests that will be directly or indirectly affected by the decisions taken on these topics.

With the publication of this study, the Instituto de Investigación en Recursos Biológicos "Alexander Von Humboldt", wants to contribute constructively to this debate[I]. The main purpose of this document is to bring closer conflicting positions regarding biodiversity and IPR, by offering an objective analysis of the different points of view. In this context, the document aims at bringing closer two international agreements that are very related thematically but very apart in their effective interactions.

Our interest is not to provide the formula to solve the debate, but to promote a constructive reflection about fundamental issues affecting the conservation and sustainable use of biodiversity. We hope that this publication contributes to a better understanding of the topics been discussed in these forums, to promote reflection and inspire possible solutions to negotiators and decision makers in these issues. Likewise, we wish that non specialists interested in the relation between intellectual property rights and biodiversity benefit from it.

Finally, we would like to emphasize the great dedication and rigorousness of the author of this publication Ana María Hernández Salgar, researcher of the Instituto Alexander von Humboldt.

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Introduction

Intellectual property rights ("IPR") are the rights given to persons over the creation of their minds.[II] They are of two types: a) Copyrights and rights related to Copyrights, and b) industrial property rights. The former refer to the creations that result in works, such as literary, musical or artistic creations. Industrial property rights refer to trademarks[III], geographical indications[IV], drawings or industrial models[V], patents[VI],and industrial secrets or information that has not been revealed[VII], amongst other things. Furthermore, there are also the plant breeder's rights, which are subject to legislation different from that governing industrial property. The former has been regulated, for the purposes of the Andean Community, by the International Union for the Protection of New Varieties of Plants - UPOV - and Decision 345 of the Cartagena Agreement, regarding a Common Régime of Protection of the Plant Breeder's Rights. This document will focus on the rights regarding industrial property that deal with the issue of biodiversity, because the protection which they can offer opens the possibility of protecting all spheres of life, whether flora or fauna. The protection of the new plant varieties will be discussed biefly, as it demands an analysis different from that of the patents regime.[VIII]

Intellectual property rights were formally introduced by an international treaty in 1883, when the Paris Convention on Industrial Property was signed, and the Union for the Protection of Industrial Property was created. Yet, the intellectual property rights which were directly related to the trade of goods and services, were structured on the postulates of the Paris Convention by the GATT Uruguay Round which led to the signature of the Marrakesh Convention, allowing for the creation of the World Trade Organization (WTO). The creation of the WTO gave origin to the development and readjustment of agreements in areas that dealt with the trade of goods and services among the Member Countries.[IX] One such agreement refers to Trade-Related Intellectual Property (TRIPS), which has today become one of the principal legal instruments in the area of intellectual property rights. The provisions of TRIPS will not come into force in developing countries until January 1st 2000, however, and Article 27.3.b will be subject to review. It is therefore important to discuss certain provisions of the agreement and restructure those that might be contrary to national interests or legislation.

In early 2000, the WTO will initiate the review of its Agreements, in what will be known as the Millennium Round. During this review, there will be discussions regarding the application of TRIPS Article 27.3.b., which has a close relationship to the protection of the components of biological diversity, such as plants, animals and microorganisms. It has been proposed that, within the scope of that Article, it would be convenient to discuss whether current intellectual rights might or might not be extended to the knowledge, innovations and practices of traditional communities. Another biodiversity related issue that will be discussed during the Millennium Round is biotechnology, which as this document will show, is relevant both to the issue of intellectual property, and to the conservation and sustainable use of biodiversity. The Member-Countries of the Andean Community have already started the review of Decision 344 regarding the Common Regime of Industrial Property, in order to present a unified position on different IPR issues, including those relating IPR to biodiversity.

The Convention on Biological Diversity is the framework convention on biodiversity issues. It's objetives are the conservation, sustainable use and the fair and equitable sharing of benefits araising out of the utilization of biodiversity. According to Article 2 of the Convention, biodiversity is conceived, at all its levels (gene, species, population, ecosystem and landscape) as the "*variability among living organisms from all sources including,inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.*"

Although at first sight the close relationship between the components of biodiversity and the law of intellectual property is not evident, this issue has recently become highly controversial. Basically, the discussion is centered on whether only biotechnological developments in plants, animals or microorganisms that fulfill the requirements of novelty, inventive status and industrial application are subject of protection, or whether it also embraces the possibility of patenting biological material in its natural state. This debate has intensified in recent years because with the application of new technologies to living organisms, and with the widespread uses found for biological and genetic resources, there has been an increase in the numbers of applications for "privatization" (i.e. exclusive exploitation), and the subsequent commercialization of the components of biodiversity through intellectual property titles.

On the other hand, attention will be given to a topic of tremendous importance for a country such as Colombia. The issue is whether it is convenient or not to protect knowledge, innovations and traditional practices by means of current IPR, or by means of *sui generis* systems. This paper will not deal with some topics of major ethical importance, such as the Human Genome Project. Biodiversity will be exclusively analyzed from the point of view of the Convention on Biological Diversity.

This study will center on current concerns regarding the incidence of IPR on biological, genetic and microbiological resources. Thus, the analysis will not only discuss the TRIPS now in force, but also those which are currently under review, and will focus on those that have connections with the objects that are subject to be patented. We do not propose to answer all the questions raised, but to offer an overview, as complete as we can, of the state of the art on this topic, to generate questions for future debates, and to try to put together all the different points of view and positions in order to facilitate the decision-making process.

This study will develop the following points in order to clarify the principal topics that bear a relation between IPR and biodiversity:

1. Biodiversity Conservation. This chapter includes a short analysis of generalities on conservation and the sustainable use of the Convention´s view of biodiversity. The most salient general aspects of TRIPS are also presented, with the existing relationship between intellectual property and living matter, particularly in connection with the topic of plants, animals, essentially-biological procedures, micro-organisms, and obtention of plant varieties. The relationship between IPR and traditional knowledge will also be analyzed, as well as the issue of the *ex situ* conservation and intellectual property.

2. The sustainable use of biodiversity and its relation with the applicability of intellectual property rights. This chapter introduces the different meanings of use that the components of biodiversity receive when they are patented or when they are protected by other IPR rights.

3. Access to biodiversity components, safety in their use, and distribution of benefits. First, the issue of access to genetic resources and the ongoing debates regarding the possibility of protecting them by means of intellectual property rights will be discussed. Biotechnology and biosafety topics will follow. Finally, the distribution of benefits and the relation with IPR will be analyzed.

4. Cooperation Mechanisms. Governmental cooperation, scientific and technical cooperation, research and education, and the follow-up and exchange of information will be analyzed.

Instituto Alexander Von Humboldt hopes that this work will be useful to anyone interested in obtaining information regarding the most relevant current and future discussions on intellectual property rights with respect to trade and biological diversity.

Bogota, 1 October 1999.

I. The Conservation of Biodiversity.

A. *General aspects of conservation and sustainable use of biodiversity-.B.TRIPS General Aspects-. C. Intellectual Property Rights and Living Matter-.D. Intellectual Property Rights and Traditional Knowledge-. E. Intellectual Property Rights and Ex Situ Conservation.*

A. General aspects of conservation and the sustainable use of biodiversity

Since the 1972 Stockholm Conference, and even before that, the international community has expressed its concern for the improper use of the environment. Twenty years later, in 1992, the United Nations Summit on Environment and Development took place. This summit gave origin to the principles of conservation and sustainable use now in place, as contemplated in "*Agenda 21*". One result of this summit was also the Convention on Biological Diversity, which is part of Colombian legislation (Law 165/94), and which is the world action framework on biodiversity.

One of the foundations or central axes of the Convention on Biological Diversity is the conservation of biodiversity. Alongside the conservation generalities and the use of sustainable components included in the Convention, we find the regulations, decisions, programs and projects that must be established or developed within national boundaries in order to conserve biodiversity and make sustainable use of its components. These provisions should, where possible, be integrated into plans, programs and to sectoral and cross-sectoral policy.

Furthermore, there are basic provisions of the Convention to prevent a negative impact on biodiversity; these are precautionary measures. The preamble addresses the issue as follows: "*Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source*", and "*Noting also that were there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat*"

Other measures which are the responsibility of States in order to achieve the conservation and sustainable use of biodiversity, relate to sovereignty and the exploitation of their biological resources. This is especially relevant when referring to access to genetic resources, in terms which must be mutually agreed, and with the consent of the country of origin or collection.

In addition, recognizing the importance of the work of the traditional communities in the conservation and sustainable use of the biodiversity, the Convention has established an obligation to protect their knowledge, innovations and practices.

The Convention articles on sustainable use refers to the measures designed to ensure that the exploitation of biodiversity will not result in its long term decline. These terms are central to the Convention, and are directly associated with the benefits that may result, and that must be shared in a fair and equitable maner among all concerned.

One way of facilitating the implementation of this provisions, is provided through access and transfer of technology to developing countries, on fair and equitable conditions. The Convention stipulates that access and transfer must respect all existing legislation on intellectual property, associated to technologies and biotechnologies.

Finally, the initiation of these basic measures of conservation, sustainable use, and distribution of benefits must be implemented by effective access to genetic and biological resources, the transfer of adequate technologies, and funding. These must be the main goal of the Convention on Biological Diversity.

B. TRIPS - General Aspects.

1. National Treatment-. 2. Most-Favored-Nation Treatment. 3. Industrial property.

In the terms of TRIPS, this study has interpreted the “generalities” as the terms which the Parties must adopt within their territory so that they will level in their international responsibilities in trade and in intellectual property rights, and that are of interest for this analysis.

1. National Treatment

One of the interesting points of commerce which also affects IPR is that of "national treatment".[1] This is one of the most decisive but indirect issues which relates to intellectual property. Basically, "national treatment" means giving treatment to foreigners no less favorable than that afforded to citizens of another State with respect to the protection of intellectual property. We highlight this point because "national treatment" can be considered as a national measure for the promotion of trade and of IPR development, and in this respect, it would be applicable to patent applications based on, amongst other things, components of biodiversity. The acceptance of special treatment in matters as complex as IPR, and the offer of equal conditions to nationals and foreigners might lead to different interpretations. In extreme cases, one might think that developing countries are taking the risk of handing their cultural or national heritage to countries with more technology, or financial capacity.

Nevertheless, from a different perspective, "national treatment" also benefits less developed countries, since they win the advantage of being able to compete under equal conditions, in the acquisition of IPR. In this context, one might say that IPR were established to guarantee certain rights to inventors, and to promote research and results. This, in turn, encourages processes of technological development linked to new inventions and to the transfer of technology. In this respect, "national treatment" also provides an incentive to inventors so they develop their products and procedures, and promote the exchange of technological developments, inherent to the inventions that IPR applicants transfer to the State where they wish to protect their invention.

2. Most-Favoured-Nation Treatment

In addition to national treatment, there is Most-Favoured-Nation Treatment.[2] This means that if a Member of the WTO grants privileges to another Member, it must also extend them to all the other Members. Although MFN is not as controversial as "national treatment", it does imply that though certain countries will obtain privileges, the development of all fields of creation of the human mind will be favored in countries where technologi-

cal and financial facilities are better. On the other hand, the MFN clause allows for a balance in the possibilities of acquiring IPR in countries with different degrees of development.

3. Industrial Property

The main interest for biodiversity in the analysis of intellectual property rights is that of industrial property. In this context, the most relevant topic is patents; geographical indications and the protection of unrevealed information come second. These are the IPR that are closely related within current and future discussions in biodiversity and IPR related issues. The analysis will focus on the theme of patents, because at this moment, there is the possibility of modifying TRIPS Article 27.3.b[3] which refers precisely to the possibility of denying excluding from patentability certain elements closely related to biodiversity. An explanation of the content of each of the issues on industrial property follows.

Patents are rights that are conceded to a private individual or legal entity for any inventions, whether of products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (TRIPS Article 27). This will be the most relevant point of our analysis, because it is the only one that makes explicit mention of the use of biological and microbiological resources in the acquisition of patents. Furthermore, it is the only intellectual property right that protects the content of biotechnological creations,[4] that is, the modifications made to a product or procedure, and not to the visible form in which the creations are presented.

Geographical indications refer to the intellectual property rights that identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin (TRIPS Article 22). This provision is important because it provides support for defining the benefits to be earned from industrial property rights in relation to the products extracted from a given country. Yet it is worth

noting that this mode of protection does not cover the content of the invention, but only the country(ies) or place(s) of origin of the base living matter and of the final result, provided that the good comply with the characteristics given above, and that the biological material is characteristic of that place or country. These indications can signal, for example, that a basket woven with a special bark or liana which is typical of a given place, comes from a specific region or country. Another classic example is that of wines, which are generally known by their geographical indications, such as "Bordeaux". This wine has earned a reputation because of the particular vines that grow in the region of France around Bordeaux, and that give the wine its characteristic flavor etc.

The protection of undisclosed information is given to information that is secret, has a commercial value because it is secret, and has been subject to reasonable steps under the circumstances to keep it secret. This provision is designed to prevent information legitimately classified secret from being disclosed to, acquired by, or used by others without the consent of the owner of the secret, in a manner contrary to honest commercial practices. (TRIPS Article 39). It is relevant here since it could provide ideas on how to protect the traditional knowledge of indigenous, Afro-American and local communities. Nevertheless, as will be shown later, the protection of industrial secrets, as currently provided for in TRIPS, is not an appropriate tool for protecting traditional knowledge. Furthermore, in the context of IPR, WTO Members have admitted that the rights regarding the protection of information refer to private rights and not to collective ones, thus denying protection for collective rights, such as those over traditional knowledge.[5] This is the starting point of a discussion as to whether the scope of current IPR régimes is sufficient to offer protection in several areas covered by the Convention on Biological Diversity.

Finally, it should be mentioned that TRIPS gives Member-States the opportunity to create and strengthen their internal laws by introducing national or regional rules for protection which are wider than TRIPS itself suggests, providing that they do not violate the terms of the Agreement. Therefore, a legally binding instrument, such as Decision 344 of the Cartagena Agreement, is stricter than TRIPS, but is compatible with the Agreement. This point will be further analyzed in due course.

C. Intellectual property rights and living matter.

1. Plants and animals-. 2. Essentially biological procedures-. 3.Microorganisms-. 4. The New Plant Varieties.

Article 27 of TRIPS establishes that Parties may exclude from patentability, among others, plants and animals other than microorganisms, and essential biological processes for the production of plants and animals, other than non-biological and microbiological processes. The use of the word "may", gives countries the freedom to choose whether they exclude them or not. At a regional level, Decision 344 of the Cartagena Agreement does not consider living matter present in nature[6] as an invention; and if there is an invention produced with products or products thereof of biodiversity, the species or breeds and the essentially biological procedures used in their acquisition are not considered patentable. Plants are not mentioned because in the Andean Community, inventions in plants are protected by the grant of breeder's right and not by patents, as regulated by Decision 345.

The Article thus identifies what may be admitted for patent protection, in accordance with the WTO guidelines and the three requirements given above, but its application is a matter entirely for the States to decide on, depending on their internal policies and legislation.

In the same Article, TRIPS explains that intellectual property may be protected by patents for inventions in all fields of technology, provided that the inventions comply with three requirements: novelty, inventive status and industrial application. In terms of intellectual property, the relationship with living matter is basically a question of protection that may be granted to the new developments in biotechnology; its scope may be extended depending on the future changes to IPR regulations. The Convention on Biological Diversity is quite open: it allows the international treaties on IPR to regulate this area. Therefore, for the purposes of TRIPS, there must be more profound studies on the granting of patents and on other intellectual property rights related to technologies based on biodiversity.

Finally, in this chapter on intellectual property and living matter, it should be noted that TRIPS Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. There are evident problems regarding these restrictions: how does one define a "danger to morality" ?

Might these exceptions not become hidden obstacles to trade of certain products or technologies? Should we perhaps question the granting of patents and the commercial exploitation of certain biotechnological products which might be harmful (such as certain living modified organisms) ? If so, would this not be an attempt to regulate an area that corresponds in the first instance to the Convention on Biological Diversity ? As we can see, the Agreement is very ambiguous and must therefore be understood in its broadest sense. The broad sense of the application of TRIPS is given in Article 1.1 of the Agreement, that allows the legislation of Member-States to be even stricter in their national regulations, provided that they stay within TRIPS parameters.

1. Plants and animals.

The scope of patent protection is addressed to both the procedures and the products of plants and animals and of essentially biological procedures. Initially, within this scope, there is no possibility of granting patents to any component of biodiversity in its natural state because there is no novelty and no inventive step involved. Yet, the doors are open to the protection of new biotechnological developments (both in products and procedures), including living modified organisms by man.

In general, this could be taken to mean that no living matter existing in nature should be patentable, because human beings have not intervened in its creation, and thus, two of the requirements for granting a patent - novelty and inventive status - can not be satisfied. This covers both biological and microbiological organisms. Nevertheless, there are conflicting positions on the point. We will consider first the case of plants

and animals. On the one hand, it could be held that the mere discovery of any unknown taxa, whether vegetal, animal or microbiological, is not an invention, and is therefore not admissible for patent protection. Likewise, if a new type of biotechnological treatment is applied to a variety in order to obtain a different variety or to improve the existing one, patent protection should be available because man has taken part in the improvement of the organism, or in the creation of a new organism which did not exist as such in nature. This is our interpretation of the regulations of Andean Community, as stated in Decision 344 on Industrial Property.

On the other hand, in countries such as the United States, national patents have been granted to discoveries, and in Europe biological or genetic material isolated from its environment may be considered patentable. Despite this, it cannot be said that these countries are infringing TRIPS, because they agree on the fact that such material is patentable if it meets the requirements of inventive status, novelty and industrial applicability. The difference in the positions lies in the interpretation of application given to these three requirements in national legislation.

Following the same line of argument as for the example for plants and animals, differences in the interpretation and interests regarding the patenting of genes or sections of genes have arisen. A gene from a plant or animal and/or its properties should not be patentable because it exists as such in nature. It can thus be classified as a discovery but not as an invention, and it does not change just because it has been isolated. Likewise, a gene that has been isolated by biotechnological means could be patentable because it complies with the requirements needed to protect inventions. Nevertheless, the States which permit genetic patents claim that the mere isolation of a gene is in itself novel, because genes do not exist in isolation in nature. Other States say that genes may not be patented unless they contain a biotechnological modification that allows some innovation and inventive status to be shown, because isolation *per se* does not change a gene.

We can thus see that the arguments regarding patent protection for genetic and biological material in plants and animals turn on the differ-

ence in interpretation that States have made of the meanings and limits of the requirements for granting patents. The implications for biodiversity and way in which the Convention applies to these differences are a matter of great controversy, not only from an ethical point of view, but also from a practical one, as will be seen later.

2. Essentially biological procedures.

With regard to the topic of essentially biological procedures for the production of plants and animals, it should be said that in general, these biological procedures are those that have not been designed, and that do not depend on human intervention for their functioning,[7] (e.g. photosynthesis). According to TRIPS, they could be excluded from a possible patent regime. The protection by means of IPR could be given in terms of innovative level when applied to the knowledge associated with the procedure, or even to conditions artificially adapted for the process to take place. The issue of the essentially biological procedures is not as controversial as that of plants and animals, because "essential" procedures have been differentiated from those which are not, thus providing greater clarity as to whether they qualify for patent protection.

3. Microorganisms.

The issue of microorganisms is much more complex because protection has already been determined at international level as part of industrial property rights. TRIPS Article 27.3.b. does not consider microorganisms and non-biological and microbiological procedures as possible exceptions from protection. In this same regard, one finds the regulations for the deposit of biological material in Rule 13(bis) of the Patents Cooperation Treaty (PCT) and in the regulations for the deposit of microorganisms for patents in the Budapest Treaty.

Although in general terms it has been acknowledged that microorganisms can be patented, the issue is also controversial. There are those who think that patenting microorganisms in their natural state should not be allowed because discoveries do not hold an inventive status and the sole fact of identifying them can not be interpreted as the result of

human invention nor of novelty. Nevertheless, this is not explicitly stated in international law, and its interpretation is even more confusing in certain regional legislation.[8]

One way to facilitate understanding of the application of IPR to microorganisms and/or to microbiological procedures would be to establish a difference between isolated microorganisms, modified microorganisms, and microorganisms in their natural state. In this way, patent procedures could be applied in a less controversial way. Article 27, mentioned above, states that microorganisms can be patented, since the exclusion applies to "...plants and animals *except microorganisms*...". According to the TRIPS rules, patented material must be inventive, novel, and industrially applicable. It is in the application of both these sections of TRIPS that the controversy originates, because the same rule can be interpreted in different ways.

Consequently, claims for patents that make use of microorganisms must indicate the degree of invention or of novelty that they contain, whether in their products or in their procedures. In this case, the reference would be to manIPRulated microorganisms and not to original ones. This is the position traditionally adopted by developing countries. Nevertheless, other entirely opposed positions can be found in the European General Directive 98/44 Article 3.2[9] which states that the protection covers the biological material isolated from its natural environment. As we can see, some States accept that the simple isolation of a material can be classified as novel or inventive, and thus may be patented. In synthesis, the argument turns on whether patents can be applied only to microorganisms which have been manipulated and to those in which man has intervened with the use of techniques, such as biotechnology, or also to those that are found in their natural and free form in their own environment. From the above discussion, it can be inferred that the procedures that have been used in laboratories to produce a protein synthesis, or other such procedures, can be patented, but the debate still continues for microbiological procedures and for non- intervened microorganisms. At all events, it is quite difficult to check whether a microorganism has been intervened or not, especially if it is remembered that the inventories in this group are still very incomplete.

4. The New Plant Varieties

Another component of great importance in Article 27 of TRIPS refers to the granting of protection for plant breeder's through patents, an effective *sui generis* system or a combination of both. Colombia, is a signatory to both TRIPS and UPOV (1978), and is a party to Decision 345 of the Cartagena Agreement on the Common Regime for Protection of Plant Breeder's Rights (1993). In this way, Colombia has acquired a tool that could be used to protect the new varieties produced by biotechnological or other processes, despite the controversies that its application generates.[10]

The negotiations for the verification of Article 27, which includes the review of the protection for plant breeder's rights, will take place in early 2000. Colombia must work out a clear position on this matter.

D. Intellectual Property Rights and Traditional Knowledge

The protection of knowledge, innovations and traditional practices is a key issue. The rights of the traditional communities seek protection since they are a cultural asset which takes account of the values and services of the ecosystems which would otherwise have to be investigated by western techniques - a complex, expensive and time-consuming process. Cultures other than western culture must be respected, and a means to protect them must be found but only where protection is framed in the context of history, its cosmovision and culture. Also, their traditions are collective and they are generally transmitted orally from generation to generation. However, even though such traditions maintain the cultural identity of these people, and are therefore known and respected by everybody in these communities, there is certain specialized knowledge which may be in the hands of only a few (or only one) individuals.

This is the case of the *mamas*, *shamans*, and *jaibanás*, the "witch-doctors" who have the wisdom to cure physical, mental or spiritual illness and the authority to manage social conflict in the community. In western societies and individual,[11] and therefore do not cover tradi-

tional knowledge held by the entire community, which would be a "collective" right even though it is stilll private to the community. In case of specialized knowledge, such as the examples mentioned above, it can be considered "individual" because only one person possesses it and according to the culture, only this person can transmit it. But the knowledge as a whole continues to be "collective" to the community because it has been obtained through years of experience. In this respect, an initial conflict in the application of IPR to traditional knowledge because at present the collective status of traditional knowladge is not taken into account, and the protection of inventions is on individual basis.

In general, it has been said that this knowledge does not have enough protection, and that the framework of IPR does not offer the kind of security required. Current norms on industrial secrets have elements that can be helpful in protecting that knowledge. However, the protection of non-revealed information is directly related to industrial activity. Because of this, it would not be proper in the first instance to say that this type of protection is suitable to safeguard traditional knowledge, innovations and practices. There would not necessarily be the industrial ingredient that would allow them to be covered by TRIPS and, furthermore, they could not be considered as private and individual. Nevertheless those traditional knowledge that are going to be commercially exploited can be protected as an industrial secret if held in the name of a legal person.

On the other hand, in the field of protection of this kind of knowledge by patent, it is necessary to study the extent to which it can be considered as novel.[12] This knowledge, due to its traditional character, has necessarily been known and transmitted for generations. In Colombia the concept implies "absolute novelty", that is, that an invention is considered novel when it has not been known before in any way. Consequently, traditional knowledge could not be covered by a patent as such, because it is generally known by one or several persons (even if only within a given community). Other countries like the United States, however, use the concept of "relative novelty": an invention is novel if it is not known through publications or other media for a determinate time

in advance of the submission of the patent application. This could be interpreted to mean that the knowledge of traditional communities is "novel", provided that it has not been made public before the application for the patent is submitted, even though it existed before. Such a situation could be common since most of the communities which possess such knowledge are culturally-isolated minority groups. In addition, it could be very difficult to prove that an application for patent protection has its roots in traditional knowledge since the knowledge is generally not recorded or is only known or used by small communities in very small geographical areas. Therefore patent applications related to biodiversity must include clear indications regarding the source of the basis of the invention, and its geographical origin.

Decision 391 of the Cartagena Agreement, on access to genetic resources, states (Temporary Provision 8) that mechanisms to protect traditional knowledge, including *sui generis* mechanisms, must be explored. So far, however, there has not been any concrete proposal by the State, nor by the Andean Community nor its Secretariat, that develops this Provision. There is therefore no practical mechanism of practical application in the region.

As can be seen, there is a debate concerning the feasibility of covering traditional knowledge within the terms of current intellectual property regimes. Some countries, such as the United States, believe that the issue of traditional knowledge should not be discussed at TRIPS, because Article 27.3 .b. specifically mentions *sui generis* systems for the protection of plant varieties, and leaves no room for further study of the protection of traditional knowledge. Other countries, such as Colombia, India, Brazil and Canada, however, are ready to study the issue within the context of the WTO, to analyze if it is feasible for TRIPS to regulate this matter, even though it is not explicit in the mandate of TRIPS. What is important here is that this knowledge is vital for the conservation and sustainable development of biodiversity. There are different ways of understanding the way that nature works, and in this sense, traditional knolwedge is a new proposal on how to use and manage the environment. On the other hand, traditional knowledge contains a rich understanding of products and procedures that could have value in medicinal products, food, etc.

In this way, the first question that needs to be asked is whether it is necessary to establish a western system of protection for knowledge that has been and is still preserved by communities through ancestral practices and customs. If the answer is that it is necessary, then we should ask in what way it would be convenient to establish a new system to protect community knowledge through national or regional process of study and research.

If a western regulatory framework were to be created for the protection of this knowledge, we could say that what is being protected is the rights of the traditional communities acquired by them for having developed their knowledge, in the same way that IPR have been established to protect an inventor's rights over its knowledge. The next question might be, what sort of protection could there be? A database is being set up in India, where the most deeply rooted knowledge and traditions are to be found, and the knowledge recorded in it will be excluded from patent protection. It is interesting that in this case the way to protect information is to make it public. However, this solution has its shortcomings: traditional knowledge could lose its commercial value, since it can not be patented because it would loose its novelty. The communities interested in its exclusive use would thus be inhibited from any industrial exploitation of the inventions that use that traditional knowledge. Also, third parties could exploit it commercially even without patent protection. Also, there is no pattern in which one could place the different concepts that the communities have regarding the way to treat their knowledge, and national laws differ in their treatment of such communities. Although the Convention on Biological Diversity calls for the conservation of traditional knowledge related to the conservation and sustainable use of biodiversity, the truth is that any study of ways to protect this knowledge would be on a case-by-case basis, depending on each community and country.

Consequently, it is not clear how the issue of traditional knowledge could be introduced into the context of existing regimes of intellectual property rights. Up to now, no legal instrument has been defined or identified which could comprehend the concept of traditional knowledge itself and the intangible components of which it is made. It could be said that, applying the earlier remarks with reference to the collective

character of community knowledge, the legal status of the community could somehow be established in a way in which better protection is offered for the needs and possibilities of the communities. Efforts have been made in this direction. For example, the World Intellectual Property Organization (WIPO) has organized consultative workshops with traditional communities, at the international level, as an exercise to discover concerns regarding IPR. In this respect, it would be convenient to promote studies and research at regional and national levels to identify alternatives for a new or *sui generis* regulatory framework. Or, in certain cases, to make the present regulations on patent and industrial secrets more specific, so that they could specifically cover the protection of this type of knowledge. It would be useful to make a presentation of the various modes of protection now available, and those that can be created or modified, in order to study the most viable ones, including the alternative of not applying protection of any kind.

E. Intellectual Property Rights and Ex Situ[13] Conservation

Here, the CBD calls for the adoption of national measures for the conservation and sustainable use of biological resources which are outside their habitat, or in *ex situ* conditions, preferably in their country of origin. Consequently, facilities to investigate plants, animals and microorganisms should be established.

For example, gene banks or banks of live material related to IPR, are incorporated into international patent norms, not so much for their role in the conservation of *ex situ* collections but because they are required to act as depositories for patents of invention based on biodiversity components. There are, however, negotiations and actions closely related to intellectual property and biological material that express strong concern for the conservation of *ex situ* collections. For example, the negotiations of the FAO Commission on Genetic Resources for Food and Agriculture is reviewing food resources listed in *ex situ* collections. Likewise, the Patents Cooperation Treaty, PCT, has regulated the deposit of biological material (including microorganisms) made in order to obtain the international registration of a patent[14]. Other international groups are also working on the IPR issue in connection with the conservation of biodiversity, *in* or *ex situ*.

When an application for a patent that uses biological or microbiological material is being studied, the samples of the material must be deposited in an institution, with the purpose of corroborating the content of the description of the invention made in accordance with the Patent Cooperation Treaty PCT, and the Treaty of Budapest on the Deposit of Microorganisms (1977). TRIPS, when permitting patents on procedures and products obtained from live material, should provide its Member-States with appropriate guidelines of institutions that might be able to handle the samples of living material, or refer them to the relevant international treaties.

A research center acting as a depositary institution must comply with the following requirements, among others[15]:

- The research center must be internationally reputed.
- The sample must be given to the center under a Material Transfer Agreement.
- The center must issue a certificate as evidence of the deposit.
- The depositor must give a copy of that certificate to the national authority to which the patent application is made.
- This certificate should specify the country of origin or collection of the sample, and a prior informed consent from that country should be legally required.
- The certificate must include tangible evidence of the consent given by the traditional communities from which the sample was taken. This applies to the case in which access to traditional knowledge of the intangible component is associated with the genetic resources and its products thereof.

According to the above, TRIPS must be more specific in the formulation of recommendations for the establishment of research centers that might operate as depositaries of live material samples for patents. The intention is to guarantee security, t national and international levels, in the handling and maintenance of the samples, and to assure compliance with other related norms. This control function should be carried out at the national level, with patent offices and deposit centers acting in concert. Naturally, the overall guidelines contained in the CBD should be taken into account when establishing mechanisms for the conservation and use of live material deposited for the purpose of obtaining a patent.

II. The Sustainable Use of Boidiversity and its Relation to the Application of Intellectual Property Rights

The analysis of the relationship between the sustainable use of the biodiversity and its application to IPR, has been focused on the use of intellectual property rights, stressing the importance of patents, greographical indications, and their relation to trade.

Article 10 of the Convention on Biological Diversity (CBD) deals with the subject of sustainable use of the components of boidiversity. It states that conservation and sustainable use tests should be integrated to decision-making national processes. CBD also points out that the Parties should adopt measures related to the use of biological resources to avoid, or reduce to the minimum, adverse effects. On the other hand, the Preamble of the Marrakesh Agreement that establishes the World Trade Organization, states that commercial and economic activities should take into account an optimum use of the world's resources, according to the objective of sustainable development. Moreover, they should also try to protect and preserve the environment. It is worth remembering that TRIPS is an agreement that depends from the previously mentioned one and therefore, the Preamble of the Marrakesh Agreement will also apply to it. In this sense, TRIPS states that if the Parties want to formulate or modify their laws, they can adopt measures which will protect health and encourage socioeconomic and technological development. It is also possible to prevent the commercialization of a patent if it turns out to be harmful for the environment, or for human health, among others.

Article 27, Number 2 of the same Agreement states that Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. As can be observed, although TRIPS by itself does not point out clear mechanisms to reduce harmful uses to biodiversity, nor is its function, it is indeed coherent with CBD's spirit. It establishes measures to prevent

illicit commerce and abuse of IPR which will adversely affect both commerce and the environment. It should, nevertheless, be mentioned that these measures are of national nature and therefore, at the time of deciding upon the granting of a patent, it is the State's responsibility to look after its compliance.

It is worth noting that use, in the context of intellectual property, is related to the exclusive exploitation rights the owner has over the invention. It is necessary to mention therefore, that the rights the holder of an IPR title has, especially over patents, are the following according to TRIPS Article 28:

"(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process".

The controversy about the use of patents granted for biotechnological substances, basically is about , firstly, the danger that the handling, manipulation, transport and release of LMOs could represent, and secondly, to the private ownership which is given to patented objects. In relation to the latter, there have been several widely criticized cases. For example, there have been attempts to patent seeds from plants that do not reproduce. For this plants, a new stock would have to be bought for each new harvest[16] . This has proveked farmers to claim rights, and has also made people understand that a possible space to privatize new products has been opened, thus affecting food security, but at the same time favoring the monopoly of agrarian trade. Nevertheless, benefits from these development can also be found since genetic transfer risks from these plants to wild parentals could be avoided. Intellectual property rights are a mechanism to encourage technological development that, although in some cases could be arguable because of its effects, can generally show beneficial effects for people, including farmers, as is the case of the protection of the obtention of new plant varieties.

Nevertheless, the privatization given to patents is not absolute and is limited in time. For example, if a product is protected for a certain use, and after being commercially exploited somebody else realices that this same product can have a second use, different from the original one, that person can present a new patent application for that second use. In the same way, any person can modify the primary protected product in oreder to obtain a new one which will therefore have a new use.

To promote a sustainable use of the biological material employed in patenting applications, and in general to promote its conservation, it should be considered that in the patenting application certain parameters could be added so that they could help clarify the purpose for the use of the biological elemnt, as well as its place of origin. In this way, the inclusion of the requirement could be proposed as [17] :

- a certificate of the country of origin of the biological sample that includes a geographical indication of either the country, region, or specific place where the sample was obtained, or the specific geographical area from which it comes.

- tangible evidence that the biological material was taken out from the country of origin with a previous informed consent.

In this way, the information obtained about origin and use of that biological material would be of great help when considering the applicability of fair and equitable distribution criteria for the benefits obtained through the marketing and use of patented products which include biological components.

III. Access to biodiversity components, safety in their use and sharing of benefits

A. Access to genetic resources and its relation to IPR - B. Biotechnology and Biosafety, its development with respect to IPR and benefits obtained.

A. Access to genetic resources and its relation to IPR.

The TRIPS agreement does not specifically mention the topic of access to genetic resources as such. However, it does discuss patenting of living matter in general, and both of these topics are closely related. In order to investigate the active components that can be extracted from plants, animals or micro organisms, with the object of producing, for example, a certain medicine, it becomes necessary to access a genetic resource or a by-product[18] from it. In other words, in order to patent living matter modified by man through modern biotechnology or any derived process, for commercial use, access to genetic resources of that material is necessary. In that context, and although TRIPS does not regulate access, there is a national and regional legislation regarding this issue, such as Decision 391 of the Cartagena Agreement concerning Access to Genetic Resources, Biodiversity Law 7788/98 in Costa Rica, and Administrative Order (ADO) No. 96-20 in the Philippines.

There is currently a general concern regarding the possibilities of patenting genetic resources, as reflected in the European Directive on Biotechnology. Again, we find ourselves in the discussion mentioned at the beginning of this analysis, of whether or not it is possible to patent the genetic resource in its natural state, and whether an isolated genetic resource has any inventive level that would deserve protection.

As noted previously, in order to be able to register a patent, any invention, and in this case those that use a genetic resource, it must have suffered some kind of human induced modification, so that it acquires a level of innovation and inventiveness, and that has an industrial application.

This is what has to be proved when attempting to obtain protection, according to Article 27, TRIPS. In other words, those scientific and technical procedures, and products derived from these procedures that are based on information extracted from genetic resources and have been modified or altered, may be patented if novelty, inventiveness and industrial application can be demonstrated. However, as mentioned previously, this opinion is not shared by those who sustain that mere isolation of the gene is sufficient for patenting.

With regard to this issue certain doubts arise. For instance, what are the existing controls over the applications of patents of living matter, considering that these must be a product of biotechnological processes and not mere discoveries? It is worth noting that it can become very difficult, if not impossible, to prove that a genetic resource which has been modified does not exist naturally, and furthermore taking into account that sequencing is different for each individual. IPR becomes a useful tool in reducing these difficulties because in the application for patents of biological material or micro organisms the applicant must present lists of DNA, RNA, proteins, nucleotides or amino acid sequences - specifying the modifications made to the material- thus justifying that there is an invention within the natural product.

The traffic of biological material for commercial use has become a main concern in environmental legislation, especially in countries of origin or collection, which generally do not have adequate infrastructure or internal legislation to react to the problem. Generally, illegal sample extraction becomes an easy method of access to genetic resources, which can then be used for creating products and processes for industrial applications. In this case, the activity is not only a crime, but it also closes all possibilities of obtaining equal and fair shering of benefits derived from access to this genetic resource between the country of origin and the obtainer.

Specialized forums have been created world-wide to deal with the commerce of biological material, such as the Convention on International Trade in Endangered Species of Wild Fauna and Flora - CITES, or forums

more closely related to the topic, such as the CBD Bioseafety Protocol under negotiation. At a regional level regulations for access to genetic resources have also been established, such as Decision 391 of the Cartagena Agreement. Even if it is true that in commercial and environmental issues there ought to be more cooperation for the control of illegal trafficking of biological and /or genetic material, in the case of intellectual property rights, international regulations such as TRIPS or WIPO agreements cannot help to stop this kind of illegal traffic. The most that can be done is to include in the patent applications an indication of the origin of the living matter which is used for an invention. Commercial and environmental national authorities are responsible for controlling the legality of the material extraction.

With regard to the regulations in Article 27.3 b (TRIPS) concerning exclusions of patentability, the Member States, on deciding the application of this regulation in their internal legislation, ought to bear in mind the norms contained in the CBD , should the states be party to both of these legal instruments. Furthermore, Member States should analyze the consequences of the possibility of patenting animals and plants on conservation, sustainable use, and the fair and equal distribution of the benefits derived from access to biodiversity. It would be convenient if patents given to natural resources were awarded only to products and/or procedures involving some kind of human technology. Other intellectual property rights, such as commercial trademarks, geographical indications etc., can be awarded to any biological material that can be commercialized, whether or not processed.

In conclusion, it can be said that the CBD must work more closely with TRIPS, so that decisions and recommendations regarding biodiversity issues may be coherent with intellectual property regulations in commerce. In the same way, TRIPS must consider the regulations established in the CBD when making decisions regarding the application of patents and other intellectual property rights related to biodiversity components. Equally, countries belonging to both legal instruments must work to regulate the access to genetic resources nationally and regionally, in accordance with international regulations and in a manner which is consistent with obligations contracted in both forums.

B. Biotechnology and biosafety - its development with respect to ipr and benefits derived.

1. Biotechnology and Biosafety.

Biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. In principle, it is developed to improve the qualities of an organism which is present in nature, adapting its conditions to man's growing needs. Biotechnology has been classified, according to its biotechnological development, into first-, second- and third-generation. However, it is easier to talk about "classical" and "modern" biotechnology. The first refers to biotechnology which does not require genetic engineering or laboratory processes, such as crossing or hybridization, while the second refers to the biotechnology which is carried out through more complex scientific processes which directly use genetic information, among other things.

Biotechnology, and especially its relation to biosafety, has become increasingly more important over recent years, mainly due to the rapid technological developments in fields such as agriculture[1], although in this field traditional technique is still above modern techniques in agricultural production. Generally, we can see that the use of living modified organisms (LMO) produced by modern biotechnology has been implemented in different industrial applications such as textiles, food, cosmetics, medicine etc. It is worth noting that IPR and the possibility of exclusivity in the commercialization of biotechnological inventions have significantly contributed to their development. This is the reason why both topics are closely related.

The use of biotechnology has brought positive impacts to man, increasing the quality and quantity of products, making products cheaper, and decreasing the loss of perishable modified products. Furthermore, microorganisms that attack certain types of contamination have been developed, as well as new vaccines, etc. However, uncertainty has increased

concerning the possibilities of an undesirable expansion of the LMOs. This expansion can mean genetic erosion in wild relatives, or in the development of super-weeds; there has also been considerable discussion related to the repercussion that the use of LMOs may have on human health. As can be seen, although biotechnology plays an important and positive role in human development and in environmental protection, it has become necessary to create mechanisms to control the negative impacts that these organisms may have on humans and on the environment.

Therefore the CDB has emphasized the need of mechanisms for the regulation, administration, handling, or controlling risks derived fron the use and release of LMOs, likely to have adverse effects on biodiversity. Article 19 of the CDB calls the Parties to adopt administrative or policy measures to provide for the effective participation in biotechnological reserach activities by those Contracting Parties, specially developing countries, to promote and advance priority access on a fair and equitable basis to the results and benefist arising from biotechnologies, as well as to provide information on this issue. For the CDB, biotechnology is conceived as a mean of use of biodiversity (as well as a way of conservation), that promotes human development, and as it has been shown its application may have positive and negative repercussions on the environment.

The Convention establishes the need to create a legally binding instrument within the scope of the CBD, to regulate security procedures in biotechnological activity, which is being negotiated as a Protocol on Biosafety. This Protocol is due to be signed in the year 2000. Its scope is the transboundary movement of LMOs, based on an advance informed agreement procedure, the precautionary approach, and the handling and evaluation of possible risks. Equally, risks to human health and the development of capabilities in developing countries are being studied, so that these countries may have access to the necessary financial and technological resources to implement all regulations established both in the Protocol and the CBD.

The relationship between the CBD and TRIPS is necessary because the biological material which has undergone biotechnological transformations, as mentioned previously, is a candidate for patent protection and thus enters the field of the protection awarded to industrial property rights. The patenting of a biotechnologically modified organism does not ensure that it is safe. This is why it has become necessary to discuss the precautions in introducing and releasing this type of inventions into the environment.

Although in TRIPS Article 27.2 discusses the possibility of not patenting a product which causes damage to life and to the environment, as noted previously, it must be remembered that damage is not always identified clearly, and therefore it is more appropriate to talk about *risks of damage*. The question is whether to wait until the specific risk can be determined, or whether to take preventive measures until there is certainty regarding this risk. For example, the WTO, SPS Agreement on the Application of Sanitary and Phytosanitary Measures states in Article 5.7 that "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time". Thus, the WTO is allowing the opportunity to acquire more knowledge about a product, before releasing and commercializing it. The CDB, in Article 8 (g), also leaves room for establishing measures related to LMO risk control, bearing in mind that in its preamble it is clearly stated that the precautionary approach is an essential component of the Convention.

The negotiation of the Protocol on Biosafety is clearly a forum which has contributed to the discussion regarding precautions in the handling of biotechnological products. In principle, it seeks to establish

general measures for avoiding risks in the introduction and release of biotechnological LMOs into the environment. Currently, this has been reduced to working on the safety measures which must be taken when transboundary movement of these organisms, leaving to national legislation the regulations of risks to biodiversity and human health that may be caused once introduced in a particular environment. This discussion has been closely related to the WTO. This negotiation is gaining a significant commercial connotation, moreover when the focuss is not on establishing safety measures for release these organisms, but to regulate their safety between the movement of importation and exportation, wich is a commercial issue. Nonetheless, it must be understood that the real objective behind moving these organisms may be to apply LMOs both to scientific research and to commercial activity.

In the case of commercial activity, TRIPS is also relevant, pointing out that measures must be adopted to control the commerce of goods related to infringement of intellectual property rights. As noted previously, the patenting of living matter is currently subject to much international discussion, because it involves a product which can be both privatized and commercialized. We must not forget that LMOs are biotechnologically modified living matter, and this alteration can in many occasions result in innovation, inventiveness and industrial application, and may therefore eventually be patented. It is important that, in biotechnological terms, TRIPS and the CBD establish close links, with the objective of ensuring that LMO patenting and its later commercial exploitation does not endanger biodiversity. In doing this, priority must be given to conservation, sustainable use and fair and equal distribution of biodiversity benefits, ensuring that these objectives will not become technical or tax barriers in the trading of biotechnologically modified organisms.

Some may consider important to ask how and when LMO patents should be allowed, ensuring that both the procedures for obtaining them, as well as the final product (the modified organism), will not have repercussions on the environment, fauna, flora and human beings. It is

also relevant to question whether the study of a LMO patent application that may be harmful should no put in evidence damage against public order and morality. Doubts regarding establishment of trade barriers are also relevant, and also the possible overlaps that may arise between international treaties regarding the environment and the trade ones. However, despite the many questions the issue may bring out, international property rights were not created to question the benefits or damages arising from a particular invention. This is an issue which must be discussed in other sectors such as environment and trade. Although TRIPS states that the Member States must account for public health protection measures within their legislation, pointing out that patents can be denied to inventions that are a threat to public health, life and the environment (Art.27.2) and the SPS states in its preamble that Members are free to adopt and apply necessary measures for the protection of life and health of humans and animals as well as plant preservation, responsibility regarding this issue is mainly given to the health and environmental authorities.

2. THE SHARING OF BENEFITS

Although TRIPS does not specifically mention the sharing of benefits, in the terms that the CBD conceives it[20], it can be understood that through the promotion of technological development derived from the patents, mechanisms are established in the participation of benefits obtained from research, production and commercialization of biotechnology.

The royalties that an inventor may earn as a result of a patent are private and individual. Therefore, it is necessary to study how countries of origin or collection of biological and/or genetic resources can negotiate the economic and social benefits which are expected from allowing access to these resources with the patent holder. The Convention offers some general ideas concerning this issue in Article 19, but until specific mechanisms for calculating how these benefits can be distributed are developed by the international community, it is the State's responsibility to implement adequate measures internally.

Intellectual property rights may become a useful tool for equal distribution of benefits resulting from access and use of genetic and biological resources. This is because patenting these products not only means profit for the inventors, but also for the countries of origin of these resources. All this is based on the assumption that the regulations in TRIPS can complement the objectives of the Biological Diversity Convention, and all national regulations regarding access to genetic and/or biological resources.

It must be remembered that IPR were created to protect technological inventions (among others). However, given that real or potential value has been discovered in biodiversity resources, such as genetic resources, and that there has been an increase in the application of technology to life forms to derive procedures and products, intellectual property rights have also had to adapt to the new invention requirements in this field. Because these patented products and procedures are based on living matter extracted from a jurisdiction or territory of a State, involving previous informed consent for acces, measures must be adopted to ensure that inventors´ investment and opportunity costs are conmesurate to the costs incurred by the State in conserving these resources.

IV. Cooperation Mechanisms; relationship between regulation of intellectual property and biological diversity.

A. Intergovernmental Cooperation. B Scientific and technical cooperation. C. Research and education. D. Follow up E. Information sharing.

A. INTERGOVERNMENTAL COOPERATION.

In the CBD, cooperation must be guided towards the States and international organizations (governmental and non-governmental), with the objective of conserving and sustainably using biodiversity, and according to common interests that may link different institutions and countries.

Cooperation between TRIPS Member States is mainly directed towards controlling commercial goods that infringe intellectual property rights. To do this, it has been agreed that there has to be a constant process of information sharing, the necessary notifications concerning commercialized products, and cooperation between customs authorities. TRIPS cooperation between governments goes beyond these topics. It not only involves cooperation with the Parties, but also works to create close links with international organisations that deal with this topic, such as WIPO with which it has a memorandum of understanding, UPOV[21], FAO[22], OECD[23], UNCTAD[24] and the World Bank, among others. However, specific cooperation mechanisms with the CBD do not exist. Despite the fact that the CBD has called upon its Secretariat to attend as an observer to the WTO meetings in order to exchange information (Decision CBD/III/17), the Convention´s presence in the Trade and Environment Committee and the TRIPS Council in the World Trade Organization has been practically non-existent. To date, the Convention Secretariat has limited itself to the distribution of a number of reports to Member States concerning the activities developed within the organisms dealing with intellectual property rights, but so far there have been no conclusive results[25] .

As there are currently numerous debates among the international community regarding the relationship between IPR, trade and biodiversity, it has become necessary for the Convention to play an active part in WTO meetings and negotiations, both in the Trade and Environment Committee and in the Agreement on Intellectual Property Rights. This participation must be reciprocal, and must take into account all of the questions raised by Member States. To achieve this objective it is necessary to create stronger links, and not merely act as observers. Cooperation memoranda could be established between TRIPS and the CBD regarding the development of the key articles that deal with intellectual property rights related to biological resources in the Convention.

The patenting of living matter is a topic which necessarily links TRIPS and the Convention, and as long as the debate is carried out in two separate forums, it will remain difficult to try and solve problems related to biological, ethical, moral, technical, commercial and even religious issues. If debates were to be held jointly, this could be a very useful way of identifying and clarifying certain differences. This is why an urgent call must be made to the CBD to implement decisions resulting from the Conferences of the Parties regarding intellectual property rights issues, and to study the various repercussions of IPR related to biotechnology in biodiversity within WTO.

B. SCIENTIFIC AND TECHNICAL COOPERATION

TRIPS, through its Council (its senior organ), has been working on the issue of science and technology cooperation, directed mainly at the developing countries and especially at producers and users of this technology. According to the Council, cooperation must be focused on the social and economic benefits of Member States, and to contribute, in first instance, to technological innovation, its transfer and dissemination. For some Member States - developing countries - the practical results of that cooperation has not yet produced concrete results.

The CBD emphasizes on the importance of scientific and technical cooperation, although its objective is obviously different to that of TRIPS. As far as the Convention is concerned, development and technology transfer must be based on the conservation and sustainable use of biological diversity. Encouragement in the use of technologies includes, among others, local and traditional technologies. As can be seen throughout this analysis, a fundamental focal point between the Convention and TRIPS is biotechnology. This is why the importance of cooperation and technology transfer is essential when studying both treaties.

Up to now there has been no balance between the technical and scientific capacity of developed countries in comparison to developing countries, most of which, paradoxically, possess the greatest biodiversity in the planet. Their natural resources are the raw material for the development of biotechnological processes, through research into the components that can create new technologies. However, in the majority of cases, the countries that possess these resources do not have the technological or financial capacity to conduct research. The Convention establishes that access to resources must be accompanied by technology transfer, as an essential component of achieving its objectives. Furthermore, in the case of access to technologies, a special space is opened to developing countries, enabling them to obtain these technologies under fair and most favourable terms. However, and even though TRIPS mentions the importance of this issue, it has not yet discussed exactly how this transfer is to be effected, and this is a fundamental consideration in enabling the less developed countries to exploit their own resources, or at least to set the basis for explore their technological capacity.

In this field, the CBD, through its Clearing-House Mechanism (CHM), has begun to strengthen scientific and technological cooperation. TRIPS is also encouraging technology transfer, and both treaties coincide in stating that priority ought to be given to developing countries. However, countries that have these resources have not yet received any concrete results regarding technology transfer, or priority access that would enable them to develop their resources, both in the bioprospection and biotechnology fields.

Good intentions must not simply stay on paper: mechanisms must be created to produce concrete results for the Member States. So far technological and scientific cooperation has been restricted to financing specific projects in countries, but no global mechanism has been created for all of the parties involved. The CHM, in the case of the CBD, can be considered a first step in providing an appropriate mechanism, but up to now cooperation has been restricted to information sharing. TRIPS has not developed an adequate mechanism to deal with the problem of technology transfer in intellectual property issues related to trade. In Article 7 TRIPS mentions that IPR protection and observance must contribute to technological innovation and transfer, to benefit both technology producers and users, in order to create a balance in rights and duties, as well as economic and social stability. The only method that the WTO text offers is that Member States at the national level should establish adecuate mechanisms, and report the resulting cooperation activities. Is this enough to make technology transfer in the terms established in TRIPS a reality?

It is clear, that it has become necessary to create a process of technological and scientific cooperation and transfer, in order to balance responsibilities, opportunities and benefits to all parties members of one treaty or the other. To do this TRIPS must create some kind of a mechanism in the same way that the Convention has created CHM, specifically called upon to develop these issues, and to design plans, programs and measures, nationally and internationally, for scientific and technological development of all Member States.

C. RESEARCH AND EDUCATION

The Convention emphasizes the need for developing countries to establish training and education programs in science and technology, as well as in research, especially guided towards biological diversity areas.

Regrettably, TRIPS does not consider the issue of research and training, even when discussing technology transfer[26]. If no mechanisms for handling and developing technology exist, how can any progress be made by the less-developed countries? It would be desirable that developing

countries which hold biological resources with potential industrial use could develop their own methods, thus adding value to their resources, so that these countries could exploit their biological richness in the same way as developed countries do. Again, this is why an adecuate technology transfer becomes essential. Training and education programs in developing countries must be strengthened, so that they can implement and develop technologies. To do this, courses should be designed, such as the one arranged by TRIPS and WIPO ("Technical cooperation guided towards improving human resources and institutional capacity required to apply the regulations about TRIPS, regarding national observance.") Training and education programms, must also be open to anyone who has an interest in research in biotechnology. This type of support for research must not only come from the international offices, (TRIPS Council or Convention Secretariat), but it must also be an initiative of the countries which have some knowledge of the subject and can share it.

TRIPS has also abandoned the issues of public awareness and education, even though it is backed by WIPO, whereas the CBD is beginning to implement measures designed to improve this aspect, especially dealing with education in the development of national strategies and plans of action, as well as initiatives to inform the community about the regulations in the Convention. Within the work plan designed by the COP in the CBD, education is a key factor in all areas discussed. UNESCO is invited to consider launching a global initiative for education, training and public conscience in biodiversity issues.

The WIPO has undertaken the task of disseminating information regarding IPR, and TRIPS has agreed that it should remain responsible for this aspect. WIPO does have some specific mechanisms for education, such as seminars, workshops and conferences. These mechanisms are all addressed to issues regarding the regulation of the treaties under its wing, and make only tangential reference to TRIPS. Despite the cooperation memorandum between the Convention and WIPO, perhaps the WTO should consider strengthening knowledge about TRIPS, especially now that the Millennium Round is close, and with it, the review of TRIPS Article 27.3b. It is also worth noting that not only those

dedicated to intellectual property rights should work on the subject, but that anyone interested should have information on this subject. This is because any individual can invent something which could be patented, and ignorance regarding mechanisms may result in the loss of recognition for the invention. There is a certain amount of alarm among the international community regarding the patenting of living matter, and this is largely due to the lack of information about TRIPS, and its application both nationally and internationally.

Issues concerning education must be discussed in each of the TRIPS Member States, so that national intellectual property offices may illustrate the population about the IPR legal regime in each country, policies to adopt, and international responsibilities. TRIPS, through its Council, must call upon its Members to design national education plans in intellectual property rights, as well as attempt to offer adequate financing mechanisms.

D. FOLLOW UP.

The follow up of TRIPS and the CBD refers to the supervision needed to ensure that each one of the treaties is being complied with. However, given their close relationship in certain subjects, it would be interesting if TRIPS were to establish a specific regulation for patents in biotechnology, so that origin, commercialization and effects can be clarified. Although this task is being performed by national intellectual property offices, it would be convenient to centralize this information internationally, so that it can be made available to the public in general. Supervising patented (or in the process of patenting) biological products and procedures can be a good mechanism for implementing biosafety measures concerning the trasboundary movement and trade of living modified organisms that are in one way or another covered by an intellectual property right. In doing this, account should be taken not only of TRIPS regulations and procedures used in the National Patent Offices, but also of other WTO regulations, such as SPS. All of this is designed to make regulations regarding the trade in biotechnology more coherent.

A fundamental supervising mechanism within the scope of CBD, is the establishment of procedures to evaluate the activities that are likely to have significant adverse effects on biodiversity. In the case of TRIPS, this topic is not dealt with, either in the text or in the annual reports, apart from Article 27, which mentions the possibility of denying a patent when grave danger to the environment is imminent. However, this is a highly subjective measure, as it gives the parties the discretion to decide whether the trade in certain types of inventions is dangerous.

An evaluation of environmental impacts in the case of intellectual property rights is very complicated, because it is not reasonable to include measures to evaluate possible risks of a patent application that contains living matter. The best mechanism is supplied by the users of the patented products, which have the power to avoid or minimize trading of products that could be harmful to the environment and to human life. However, it would be convenient to create or improve cooperation and information channels between national intellectual property offices and national agencies responsible for environmental issues.

E. INFORMATION SHARING.

This subject is covered by Article 17 of the CBD. The Article points out the importance of sharing information regarding biodiversity conservation and sustainable use. This exchange of information must include results of scientific, technical and socio-economic research. It must also contain information regarding training programs, local and traditional practices, and repatriation of information where viable.

To facilitate information sharing, the Convention has devised CHM (as mentioned previously), which is closely related to scientific and technological cooperation. This mechanism has established some focal points (Member States and Secretariat), and some topical points (issues of interest to the Convention) in order to organize the information. CHM is working through websites in different countries[27] and international organizations, connecting them up to the Convention Website, http://www.biodiv.org

TRIPS mentions various kinds of information: first, the need to divulge patent applications before titling them, and second, whether information exchange has been practiced or not. In the first case, publicity of an invention is required when a patent is requested and when the applicant facilitates information concerning applications and patents issued abroad. It contains an entire section that deals with non-divulged information, in order to guarantee protection against unfair competition. Second, it states that the Parties must publish all laws, regulations, decisions or administrative resolutions relating to TRIPS. However, this will not force Members to disclose confidential information that may impede the application of the law, or that is contrary to the public interest, or that may harm the legitimate commercial interests of private or public companies.

Although TRIPS stresses the importance of sharing information, it has not yet centralized this mechanism properly. Although it has a page on the WTO website, (http//www.wto.org/wto/intellec/intellec.htm) the information to be found there is in general poor. It should be extended to include databases concerning patents applied for and granted in the Member States, workshops and courses, programs, addresses of national intellectual property offices, etc.

This system of information is important, because it would provide the community with access to patent applications lodged in the Member States, and the level of inventiveness or novelty in the new application could be appreciated by the community in general. It would also act as a means for supervising the grant of patents and other intellectual property rights which might be relevant. Access to this kind of information also contributes to the transparency of all patent processes that could create controversy with regard to the environment, especially in cases where living matter is involved.

It would also be convenient to create a direct link between TRIPS and the Convention websites, in order to facilitate information sharing for any issue of common interest.

FINAL COMMENTS

Throughout this analysis we have been able to observe that WTO Agreement on Intellectual Property Rights, has a very close relation to the main themes of the Convenition on Biological Diversity. Up to now, TRIPS has been not too much active to specific biological considerations, although it does take into account the environment. For some countries, as the United States of America, it is convenient that the distance be maintained, but other countries, such as Colombia, consider necessary a study of the relations between intellectual property and biodiversity.

The existing relation between TRIPS and the CBD mainly focuses on the patents that can be granted to certain biotechnological developments in plants, animals or microorganisms, that can be subject of patentablity. These should include enough elements of inventive step, industrial applicability and novelty. This topic is being widely debated now because of the different interpretations that can be given to TRIPS specifications. However, the idea of applying IPR to biodiversity goes beyond patents, if one takes into account that geographical indications, trademarks and industrial secrets can be equally related to the marketing and privatization of tangible and intangible components of biological diversity. The discussion derived from this topic is mainly focused on which of these components would be subject to this type of protection.

As was noted throughout the analysis, TRIPS requires novelty, inventive step, and industrial applicability as the basic conditions to start patenting procedures. In this way, the components of biological diversity that could be included in this system would be those transformed or manipulated by man. This means that we would not be talking about patenting wild life matter as such (an issue which could be considered as the possibility of privatizing biodiversity) but of patenting life matter which includes a certain degree of human intervention. Nevertheless, TRIPS allows Members States to decide what is, or is not, patentable within the framework of the Agreement. Some States consider

that, for instance, the mere isolation of a gene makes it patentable. In this way, the United States, the European Union and the Andean Community of Nations, despite being member States of the Agreement, have considerable differences in their regulations related to the enforcement of TRIPS Article 27.3.

It could be said that TRIPS may, at the end, be contradictory in its specifications on the patenting of microorganisms. The prerogative which the Agreement gives to the States in relation to their will of accepting, or not, the patenting of animals and plants, does not include microorganisms. Therefore, on a first reading, it could be considered that they are indeed included in the protection of the Agreement. However, when the three requisites for granting patents are considered (novelty, inventive step and industrial applicability) non-manipulated microorganisms would automatically fall outside the scope of TRIPS. Thus, in the revision of Article 27, it would be convenient to specify which type of microorganisms and / or microbial processes could be patentable, and which could not, explaining the difference between man-manipulated and non man-manipulated microorganisms.

It is not convenient to assert that some States, with technological and financial capacity, are trying to take possession of the genetic and biological resources of the less developed ones. Essentially, the biopiracy problem meaning the illegal access to resources for research or commercial purposes, and extended to the application of IPR to their products, is usually an activity undertaking by natural persons, and sometimes, by multinational companies. This is no an excuse for States to omit, in their internal legislation, the regulation of access to genetic resources and its derivatives. In relation to the access to genetic resources, TRIPS does not regulate the topic; however, some specifications included in the norm, such as geographical indications, can be useful when trying to know the origin of the live matter used in patents. Additionally, a closer way to involve TRIPS tools when making a follow up to the live matter being accessed, would be to include, as a requisite in the application forms, a previous informed consent as well as an origin certificate from the country where the live matter was collected.

It should be stressed that international legislation, and specifically TRIPS, provides tools to protect human invention, and therefore, in its essence, it cannot open the door to biodiversity piracy. TRIPS has been forced to study the applicability of intellectual property rights in an area for which it was not designed: biodiversity. Because of this, some incongruence has been found at the time of establishing the most appropriate criteria for the development of technology through patents. This doesn't necessary imply that these incongruencies are harmful for the conservation and sustainable use of biological resources.

As was previously stated, there are several tendencies at international level, on whether it is possible or not to patent biological and / or genetic material. A clear case is the European Directive on Biotechnology – Directive 98/44/EC from the European Parliament and from the Council of July 6, 1998 – in its Article 3.2. In addition, U S has allowed the patenting of discoveries of isolated genes. Although both legislations do not interfere with our internal normativity, they can at some point be applied to colombian biological resources that can later be extracted and manipulated in Europe or the United States. On the other hand, in Colombia and in the countries of the Andean sub-region, a tendency can be seen which forbids the patenting of live matter existing in nature. Nevertheless, regional regulation on industrial property is being modified (Decision 344 from the Cartagena Agreement). Colombia could present defective legal legislation concerning the regulation of intellectual property rights when considering live matter, created or transformed, its trading[39], use, and benefit distribution, since it is only now that modifications redifining the theme are being written. It cannot be denied that some countries have received international pressures to adopt the widest interpretation allowed by WIPO, related to the patenting live matter. It is also true that there is pressure to transform into international legislation some measures which up to now have been regional. There could be some problems if these measures contradict the conservation and sustainable use of the components of biodiversity, or if they induce an unfair distribution of the benefits derived from their use. Therefore, if a clear normativity is established at national level, and CBD regulations are taken into account, an equilibrium could be obtained among the interests of the countries in relation to live matter patenting.

The wide scope, or ambiguity, with which TRIPS regulates patentable live matter, establishes a complex legal framework that may have voids. Up to now, Andean Resolution 344 has ruled over industrial property with the purpose to protect and respect biodiversity. Nevertheless, national and regional legislations from other parts of the world, and the same WTO discussions, have encouraged CAN members to drastically modify the current concepts on the topic, especially those related to biotechnology, in order to adapt the legislation to the positions held inside TRIPS.

In relation to this topic it must be mentioned that by making a specific regulation we do not intend to establish laws which would leave us outside from the international scope. On the contrary, since Colombia is a member State of WTO, it must be alert to encourage technological development and free trade in a transparent and fair way.

The formal relation between TRIPS Council and CBD's Secretariat can be substantially improved. The CBD, under the command of its Conference of the Parties, should be much more specific in its recommendations for concrete actions related to the development of Article 16, and of all those articles which could be associated to intellectual property rights. It should also specify more clearly the function of its Secretary in relation to the ties that could be established with TRIPS Council.

In this same context, biosafety is a transcendental topic at the level of the Convention on Biological Diversity, and it is closely related to TRIPS. A conclusion we may draw from this analysis is that it is important to promote development on biotechnology, but cautiously, especially in the movement, use and handling of patented LMO. Whether or not granting IPR to modified live matter, should be a prerogative of the State and its regulation should be coherent with national needs and international expectations. Thus the importance of knowing the causes and consequences of the use of the components of biodiversity in biotechnological proceses, and their patenting.

TRIPS may have a lack of structure when considering the the protection of knowledge, innovation and traditional practices to which the Convention on Biological Diversity refers. Especially to provide an adequate protection to traditional knowledge, according to CBD's spirit. This is understandable since the Agreement was established to protect individual and private industrial inventions.[40]

As has been seen, the knowledge of a traditional community is not necessarily covered by this frame. Therefore, it would be advisable to encourage the participation of traditional communities in workshops that deal with intellectual property, so that they can express their opinions and points of view. In this way, a process of analysis can be started for the type of protection which should be given in the legal compass of their knowledge. Some of the aspects provided by IPR can serve as a basis to promote certain protection criteria. For example, geographical indications can back the origin of the procedures and products, resulting from traditional knowledge, and the protection of the undisclosed information can support the creation of mechanisms to study the way to prevent them from being acquired against the consent of the owners of this knowledge. On the other hand, besides the ideas obtained from TRIPS, it is necessary to take into account that, within CBD an ad-hoc working group on traditional knowledge has been established, and it would be convenient that they could work on this theme. Also, at regional level, and according to the composition and characteristics of the native population, more concrete legislation can be set, as Decision 391 from the Cartagena Agreement establishes.

It can be expected that in the coming negotiations on the implementation of TRIPS Article 27.3.b, both the WTO measures established on trade and patents and the decisions and recommendations of the Convention on Biological Diversity, be taken into account, with the aim of having closer relations.

In the recommendations that will be proposed to TRIPS Council, it is necessary to stress the importance of control measures to the deposit

of live matter samples in research centers. This has to be done with the purpose of protecting not only *ex-situ* collections that can be created, but also the information that can be drawn from those collections. This purpose can be obtained if the patent applications require certificates of origin and previous informed consent from the country which has provided the resources.

As the importance for the use of biological material in industry widens, the possibility for an unlimited access to resources increases. Therefore it is important to have national control over the traffic of biological material (being it an import or export product), especially in countries that are centers of origin and of genetic diversity. For this purpose, Colombia has Decision 391 from the Cartagena Agreement, related to the access of genetic resources. Intellectual Property Rights cannot support the control of an illicit traffic of biological or genetic material. However, they could establish the origin of the samples of live matter used for patenting, through the implementation of geographical indications so that at least, the origin of that material is known.

A sustainable use of biodiversity related to intellectual property rights should be seen as a means to encourage biotechnological development. It should also take care that any process or product protected by IPR will not have a negative effect on the environment in general, or on the tangible or intangible components of biological diversity in particular.

Throughout the analysis, the necessity of putting into practice a true process of cooperation and transfer in the scientific and technological fields, has been evident. It should allow for an even share of responsibilities, opportunities and benefits of all Parties belonging to CBD and TRIPS. Inside TRIPS, especially in its Web page, information related to those intellectual property rights that have been applied for, and granted, should be more complete. In this way it would be easier to review the state of the art; it could also be possible to make a detailed follow up to the applications and titles granted. Furthermore, it could also contribute to know which applications and titles are directly related to biological material or its derivatives.

Finally, it is urgent to start with education measures on the meaning and scope of intellectual property rights. This can be done through programs, workshops, courses or brochures which spread out information on the topic. Colombia, due to its biological wealth, will certainly have to consider applications related to bioprospection, for scientific research and trading of its resource components which, when modified, will be patented. If decision-makers, national researchers, industry and academics understand both IPR's scope, and the implementation of the CBD objectives, it will be possible to overpass prejudice that currently impides to see a sustainable development and the benefits which may be obtained through a sound national management of our international obligations.

ABBREVIATIONS

DNA: Desoxirribonucleic Acid
TRIPS: Agreement on Trade-Related Intellectual Property Rights

RNA: Ribonucleic Acid
WB: World Bank
CAN: Andean Community of Nations (Comunidad Andina de Naciones)
CBD: Convention on Biological Diversity
CHM: Clearing-House Mechanism for the Scientific and Technological Cooperation of the Convention on Biological Diversity
CITES Convention on International Trade in Endangered Species of Wild Fauna and Flora.
COP: Conference of Parties
IPR: Intellectual Property Rights
FAO: United Nations Food and Agricultural Organization
GATT: General Agreement on Tariffs and Trade
GEF: General Environment Facility
ICA: Colombian Agricultural Institute (Instituto Colombiano Agropecuario)
MFN: Most Favored Nation
OCED: Organization for the Cooperation and Economic Development
WTO: World Trade Organization
WIPO World Intellectual Property Organization
LMO: Living Modified Organism
PCT: Patents Cooperation Treaty
NT: National Treatment
IUCN: International Union for Natural Conservation – The World Conservation Union.
UNESCO United Nations Education, Science and Culture Organization
UPOV International Union for the Protection of New Varieties of Plants
CNUMAD United Nations Earth Summit on Environment and Development.
UNCTAD United Nations Commision for Trade and Development.

[I] It is worth noting that this study does not reflect the position of the Government of Colombia on these issues.

[II] Definition taken verbatim from the World Trade Organization Web page, TRIPRS section, address: www.wto.org/wto/spanish/intellesp/derech.htm.

[III] Any sign or combination of signs that may help to distinguish the goods and services of one business from those of another.

[IV] Those which identify a product as being originally from the territory of a Member-State, or from a region or area of that territory, when a given quality, reputation or any other characteristic of the product is basically due to its geographical origin.

[V] Schemes of independently-created new or original drawings.

[VI] Inventions, whether of products or procedures, in all fields of technology, provided that they are new, represent inventive activity, and have industrial application.

[VII] In general, to secure effective protection against unfair competition.

[VIII] For further information regarding the protection system for new plant varieties refer to " Análisis de UPOV a la luz de la Convención sobre Diversidad Biológica" Instituto Alexander Von Humboldt. Programa de Política y Legislación. 1999.

[IX] Under the umbrella of the Convention which establishes the WTO, the following appendices were developed:
Appendix 1:A. Multilateral agreements on the trade in goods (agreements on tariffs and trade, agriculture, sanitary and phytosanitary mesures, textiles, technical barriers to trade, investment mesures, prior inspections, rules of origin, procedures for the acquisition of permits, subsidies and countervailing mesures, safeguard clauses). B. General agreement on trade in services; C. Agreement on trade – related aspects on intellectual property rights.
Appendix 2: Understanding in areas concerning rules and procedures for the settlement of disputes.
Appendix 3: Trade Policy Evaluation Mechanism.
Appendix 4: Plurilateral trade agreements (on civil commercial aircraft, public procurement, dairy products, beef).

[1] Article 3: National Treatment. 1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS. 2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

[2] Article 4: *Most-Favoured-Nation Treatment*: With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member: (a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property; (b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country; (c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement; (d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

[3] Article 27.3.b says that "Members may also exclude from patentability: b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement".

[4] Nevertheless, it should be noted that the UPOV system equally protects the obtaining of varieties and their content; but as noted at the beginning of this section, this analysis deals with industrial property in connection with biodiversity. Therefore, other protective measures, such as the rights of obtainers of vegetal varieties are not discussed here in depth.

[5] Traditional knowledge is not always collective knowledge. It is sometimes entrusted to individuals, and this fact may change its status.

[6] Decision 344, Article 6 states that: the following won't be considered as inventions: b) the ones that have as their subject already existing matter in nature or a copy of the same matter..."

[7] According to Florez, Camilo, researcher of Instituto Alexander Von Humboldt. Likewise, Directive 98/44/CE of the European Parliament and Council 6/7/98 regarding the legal protection of biotechnological inventions states in Article 2. 3, that a procedure for new plant varieties or animals is essentially biological if it consists entirely of natural phenomena such as animal breeding or selection.

[8] Article 53 of the European Convention on Patents, regarding exceptions, establishes that*: " European patents shall not be granted in respect of ...b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."* Here, one can notice, that in taxative form, they are stating that the processes, and the products derived from microbiological processes are not part of this exception, but they do not except microorganisms as such. Because of this, one could infer that European legislation would not consider the possibility of granting patents to microorganisms in their natural state, although this depends entirely on the interpretation one makes of the regulation.

[9] Article 3.2. says that the biological matter isolated form their natural surround or produced by tecnnical process could be object of an invention, even if it exists before in natural satate.

[10] For additional information on this subject see the document "Análisis de UPOV a la luz del Convenio sobre Diversidad Biológica" Instituto Alexander Von Humboldt. Programa de Politica y Legislación 1999.

[11] the word "individual" should be understood to mean "a natural or legal person".

[12] In most countries, an invention is considered new when it has not been published or publicly used. Taken from the WIPRO webpage, – General information, international protection of industrial property, page1.

[13] According to the Convention on Biological Diversity, in situ conservation refers to the conservation of the ecosystem and natural habitat and the maintenance and recovery of viable populations of species in their natural surroundings where they have developed their distinctive properties, while ex-situ conservation is related to the conservation of components of biodiversity outside their natural habitats.

[14] The Treaty of Budapest, also a WIPO document, regulates the deposit of microorganisms for patent applications. Colombia, however, is not a party to that Treaty, and Rule 13Bis of PCT (as part of the Law 463 of 1.998 that aproves the PCT in Colombia) establishes the mechanisms to decide when to deposit biological material in general with the purpose of obtaining a patent, without diminishing obligations under the Budapest document.

[15] Proposal contained in Biosíntesis No 5, Instituto Alexander Von Humboldt. “Derechos de Propiedad Intelectual y Biodiversidad”. August 1998.

[16] This technology, known as “terminator”, was developed by Monsanto, and up to now there is no evidence of its use for commercial purposes.

[17] Excerpts from the Alexander von Humboldt Insitutute Bulletin Biosintesis No. 5 “Derechos
de Propiedad Intelectual y Biodiversidad”. August. 1.998

[18] According to Decision 391 of the Cartagena Agreement on a Common Regime on Access to Genetic Resources (July, 1.996), a by-product is “ a molecule, a combination or mixture of natural molecules, including crude exctracts of live or dead organisms of biological origin that come from the metabolism of living baings”.

[19] Some results of biotechnology applications in agriculturre have produced resistent harvests, more effective pest control chemicals, etc.

[20] Article 19.2 of CBD mentions that “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. Such access shall be on mutually agreed terms”.

[21] Union for the Protection of New Varieties of Plants.

[22] United Nations Food and Agriculture Organization.

[23] Organization for the Cooperation and Economic Development.

[24] United Nations Comission for Trade and Development.

[25] Documents UNEP/CBD/COP/3/23 and UNEP/CBD/ISOC/5.

[26] Even though art. 7 of TRIPS states that IPR should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, in practice these words are only intentions. Therefore developing countries are proposing an analysis to put in practice this article during the Millenium Round that will start in the year 2000.

[27] The address of the colombian CHM Web Page is: http://www.humboldt.org.co/CHM

[28] Although an ICA resolution has just been appointed, which regulates and establishes the procedures for introducing, releasing and commercializing genetically modified organisms. However, it does not specify their intellectual property régime.

[29] It is worth noting that traditional knowledge is not commonly known by "western" cultures. It is, therefore, quite complex to establish if an invention which uses that type of knowledge can be classed within the state of the art, or whether it can be considered as an innovation. Moreover, the collective character of knowledge could indicate that it was known by the public (at least within the same group) and therefore, it would not fulfil the requisite of novelty. If a third party acquires that type of knowledge and protects it through IPR, the person in charge of examining the state of the art of that application will not probably have enough tools to determine its pre-existence.

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NOTES:

[I] Definition taken verbatim from the World Trade Organization Web page, TRIPRS section, address: www.wto.org/wto/spanish/intellesp/derech.htm.

[II] Any sign or combination of signs that may help to distinguish the goods and services of one business from those of another.

[III] Those which identify a product as being originally from the territory of a Member-State, or from a region or area of that territory, when a given quality, reputation or any other characteristic of the product is basically due to its geographical origin.

[IV] Schemes of independently-created new or original drawings.

[V] Inventions, whether of products or procedures, in all fields of technology, provided that they are new, represent inventive activity, and have industrial application.

[VI] In general, to secure effective protection against unfair competition.

[VII] For further information regarding the protection system for new plant varieties refer to " Análisis de UPOV a la luz de la Convención sobre Diversidad Biológica" Instituto Alexander Von Humboldt. Programa de Política y Legislación. 1999.

[VIII] Under the umbrella of the Convention which establishes the WTO, the following appendices were developed:

Appendix 1:A. Multilateral agreements on the trade in goods (agreements on tariffs and trade, agriculture, sanitary and phytosanitary mesures, textiles, technical barriers to trade, investment mesures, prior inspections, rules of origin, procedures for the acquisition of permits, subsidies and countervailing mesures, safeguard clauses). B. General agreement on trade in services; C. Agreement on trade – related aspects on intellectual property rights.

Appendix 2: Understanding in areas concerning rules and procedures for the settlement of disputes.

Appendix 3: Trade Policy Evaluation Mechanism.

Appendix 4: Plurilateral trade agreements (on civil commercial aircraft, public procurement, dairy products, beef).

[1] Article 3: National Treatment. 1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS. 2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

[2] Article 4: *Most-Favoured-Nation Treatment*: With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member: (a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property; (b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country; (c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement; (d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

[3] Article 27.3.b says that “Members may also exclude from patentability:
b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement”.

[4] Nevertheless, it should be noted that the UPOV system equally protects the obtaining of varieties and their content; but as noted at the beginning of this section, this analysis deals with industrial property in connection with biodiversity. Therefore, other protective measures, such as the rights of obtainers of vegetal varieties are not discussed here in depth.

[5] Traditional knowledge is not always collective knowledge. It is sometimes entrusted to individuals, and this fact may change its status.

[6] Decision 344, Article 6 states that: the following won’t be considered as inventions: b) the ones that have as their subject already existing matter in nature or a copy of the same matter...”

[7] According to Florez, Camilo, researcher of Instituto Alexander Von Humboldt. Likewise, Directive 98/44/CE of the European Parliament and Council 6/7/98 regarding the legal protection of biotechnological inventions states in Article 2. 3, that a procedure for new plant varieties or animals is essentially biological if it consists entirely of natural phenomena such as animal breeding or selection.

[8] Article 53 of the European Convention on Patents, regarding exceptions, establishes that*: “ European patents shall not be granted in respect of ...b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.”* Here, one can notice, that in taxative form, they are stating that the processes, and the products derived from microbiological processes are not part of this exception, but they do not except microorganisms as such. Because of this, one could infer that European legislation would not consider the possibility of granting patents to microorganisms in their natural state, although this depends entirely on the interpretation one makes of the regulation.

[9] Article 3.2. says that the biological matter isolated form their natural surround or produced by tecnnical process could be object of an invention, even if it exists before in natural satate.