INTELLECTUAL PROPERTY AND THE RIGHT TO HEALTH

by

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1. Introduction

This paper deals with the subject of the various relations existing between intellectual property and the right to health. Reference will be made, within the industrial property system, especially to patents, as a crucial instrument in the development of the pharmaceutical industry, which in turn has afforded the world's population greater and better access to health systems. Clearly therefore, it is by no means frivolous to suggest that industrial property protection systems, by means of patents in this case, have managed to make a profound contribution to the development and improvement of the health of the general public throughout the world, by creating a situation in which the right to health, as a first-generation human right, namely one of those relating to the individual, becomes a reality.

Clear though the above premise is, it is also fair to say that the subject of the protection of pharmaceuticals and especially drugs by means of intellectual property rights has given rise to major discussions on the world stage. Those discussions have stirred up serious antagonism, above all between developed and developing countries, and have been the cause of intensive debate at international gatherings. It is perhaps in the field of health that the most questions have been asked about intellectual property and its role as a promoter of development, as health is a factor that is crucial to the survival and welfare of mankind.

It would appear however that the differences of opinion were overcome in the course of the discussions during the Uruguay Round of trade negotiations, which culminated in the signature, by almost every country in the world, of the Agreement on Trade-Related Aspects of Intellectual Property Rights, forming Annex 1C of the Agreement Establishing the World Trade Organization (the TRIPS Agreement). The Agreement obliges signatory countries to give patent protection to drugs, along with other inventions, for a period of 20 years. There is some controversy as to the grounds on which the developing countries agreed to the proposals of the more developed countries on this subject, but what is certain is that, when an international undertaking of such magnitude has been made, any discussion of the implications that it would have for the health systems of the least developed countries seems redundant, as the political decision has already been taken.

We therefore move on to deal with another subject that is closely related but still relevant and which has given rise to serious discussion in industrialized as well as in less

developed countries, concerning access to biological resources. Access to genetic resources is a subject that has come under discussion relatively recently and has become important as the search for new drugs, new therapies and new cures in our planet's biodiversity has intensified. The search for curative substances in nature is nothing new: plants especially have long been the source of miracle cures, but now, while pharmaceutical companies continue to develop drugs on the basis of sophisticated computer work, there is a resurgence of interest in medicinal plants and in natural substances with biological properties. The event that has brought new insight into the subject is the emergence of the new biotechnology, which shortens time-spans and promises great revelations in this area. For that reason, the more powerful pharmaceutical companies are turning their attention to the planet's forests in search of plants, animals, fungi and also microorganisms that are a potentially rich source of active ingredients suitable for transformation into drugs.

This interest has at the same time aroused controversy regarding the possibility of intellectual property rights being improperly asserted in order to appropriate the products of biological diversity without corresponding compensation for the country, area, tribe or ethnic group that provides the biological resource or raw material for its development. The debate has thus focused on the need, assuming the possibility of patents being obtainable for natural products, with the exclusive rights that they bring, for there also to be the possibility of recognition and due economic compensation for the person or persons who provide the raw material. This debate has also borne fruit with the signature of an international undertaking to grant such rights in accordance with the United Nations Convention on Biological Diversity, 1992 (the CBD). The problem that has arisen has to do with the implementation of the CBD, which is presenting difficulties of a practical nature.

Another major subject that arises when the issue of the relations between intellectual property and the right to health is introduced is bioethics. It is a subject that has also been seriously debated worldwide in connection with the possibility of using intellectual property to secure exclusive rights in human body parts. The debate came into the open above all with the implementation of the Human Genome Project, whereby all human genes are to be sequenced with a view to treating a number of diseases by means of gene or genetic therapy. The legal, ethical, philosophical and religious implications of such a project, and of the idea of patenting parts of the human body, has aroused protest on the part of various groups, and it is still uncertain just what the repercussions will be for the development of society.

This paper therefore aims to take a broad, sweeping look at the patenting of pharmaceuticals, and the controversy that has arisen between developing and developed countries on the subject, and to show how that controversy was brought to an end in an international treaty; it will then consider the subject of access to biological resources as a source of raw material for the development of new drugs. The first part will thus deal with subjects like the patent system, the pros and cons of the patenting of pharmaceutical products, the relevant provisions of the TRIPS Agreement and the matter of parallel

imports and the exhaustion of intellectual property rights, the latter two being still contentious at the world level.

The second part will deal with access to biological resources and the relevant provisions of the CBD, with one or two practical examples of solutions to some of the conflicts that have arisen out of its implementation.

Finally, a third part will deal with the subject of bioethics, with special reference to the Human Genome Project and the United Nations Educational, Scientific and Cultural Organization (UNESCO) Declaration on the Human Genome and Human Rights.

2. The Right to Health

The right to health is provided for in Article 25 of the Universal Declaration of Human Rights of December 10, 1948 (the UDHR). That Article provides that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."

As we see, the State cannot guarantee an individual's right to health in the same way as the other rights could be implemented, such as the right to freedom for instance; health is therefore a product of the combined action of a series of variables, some of which are beyond human control. What the State does have to guarantee, however, is the combination of situations which, like food, nutrition, medical assistance, hygiene, etc., contribute to the improvement of health.

Within that set of variables, access to drugs and techniques for therapeutic diagnosis, and also access to sophisticated apparatus for the diagnosis, prevention and cure of disease, become essential factors guaranteeing the health of human beings.

3. The Patent System

Before dealing with the patent system, it seems appropriate to speak briefly of intellectual property in general. Intellectual property is the generic term used to designate the subjective rights that the various legal orders grant to the creators of immaterial assets of intellectual origin. Those immaterial assets may be of two kinds, namely either literary and artistic creations or distinctive signs and inventions. Intellectual property therefore establishes the protection of ideas and designs in art and technology, in industry and in trade.

It is precisely because there are differences between the protection of literary and artistic creations on one hand and distinctive signs and inventions on the other that legal literature has divided intellectual property, the overall generic term, and created two subfields called copyright and industrial property. Copyright serves to protect the manifestations of intelligence and art, and above all creations in the sphere of what is aesthetically pleasing. The important thing about this subfield is that copyright protects the conception or the form of expression of the ideas, but not the ideas themselves. That means that there may be paintings or books on one and the same subject, created by different persons; each of those persons will have his own very special way of dealing with the subject, and it is precisely the manner or form in which he does so that is protected by copyright.

Industrial property, on the other hand, relates to objects that can be used in technology and industry, meaning commercial signs like trade marks, trade names and so on, and inventions in their various forms, such as utility models and industrial designs.

Industrial creations, unlike literary and artistic creations which contribute to an environment of intellectual or aesthetic enjoyment, are characterized by their usefulness and serve a particular economic purpose.

It is therefore important to focus on patents as the means of protection for inventions. An invention may be defined as an idea that purports to solve a technical problem. This accounts for the social function that has been attributed to inventions as factors promoting development and as essential components of any economic organization. Patents, for their part, are the titles conferred by the State that attest the grant of exclusive rights to the inventor for the exploitation of his invention.

The patent is the reward or inducement that the State grants the inventor for his contribution to the solution of a problem in technology or industry. It is an arrangement between the State and the inventor whereby the latter decides to disclose and publicize his invention to society, in exchange for which the State assures him that no one thereafter will be able to copy it without his consent. The patent thus performs a twofold function as an inducement to invent on the one hand and as an essential factor of scientific and technological progress on the other. Most of the research and development that is done at present takes place on the basis of very sound patent protection systems that guarantee the exclusive right to work the invention. The world is passing through an age of modernization on such a scale that a business's most prized asset is its human resources as a fount of ideas which, with the support of a research infrastructure, has ensured that scientific progress does not come as a surprise. More important than their material stocks, in the opinion of businesses, are their stocks of immaterial products of the mind, which are what give them an edge over the competition.

Patents originated with the Venetian Decree of 1474 and the British Statute of Monopolies of 1623. While it is possible to find forerunners of patents that predate the Venetian Decree, such as the privileges granted by certain kings, doctrine has decided that the Venetian Decree is the world's first true patent law.

What the Decree laid down was that any person who in the city of Venice made a new or ingenious device and registered it at the Office of the *Provededori de Commun* (municipal registrars) secured the privilege that consisted in all other persons being prohibited from making another device identical or similar to it for a period of ten years.

For its part, the Statute of Monopolies represents the culmination of the privileges granted by the British Crown, and, by eliminating all monopolies except those relating to licenses for the exploitation or making of new products, exalts the principle of novelty and practically establishes that only those monopolies that protect a novel activity are lawful. The exception written into the Statute allowed letters patent for a period of 14 years for the exclusive exploitation, for the benefit of the true and first inventor, of any type of new manufacture within the realm. Indeed the Statute actually went further in its definition of novelty, establishing that the manufactures in question were required not to have been used by others.

While it is true that the literature regards these two legislative texts as the predecessors of the modern patent system, it should perhaps be pointed out that the Industrial Revolution, and in the course of it the invention of the steam engine, was the real generating and driving force of the patent system. This was due to the fact that, with the possibility of using machines to produce goods, and the growing demand for those goods, came a change in the organization of manufacturing industry and in people's customs. At that point another substitute for quality was introduced, namely novelty. It then became important to manufacture new goods and to devise novel ones and improve those already in existence, all of which accounted for the very real importance of inventiveness and the emerging need to provide adequate legal protection for the inventor as a means of encouraging him and promoting inventive activity.

Historically it is also important to say that the transformation of economic activity, from a limited and obstacle-ridden pursuit in the Middle Ages to the free enterprise that followed the Industrial Revolution, conjures up an economic scene in which the value of invention is exalted and which ultimately explains the universal recognition of the exclusive rights of inventors.

Now we could mention, among the precursors of modern industrial property law, the 1778 Constitution of the United States of America, which allowed Congress to grant authors and inventors exclusive rights in their works and inventions for a specific period, and from which in turn emerged the 1790 Patent Act; one could also mention the French Law of 1791, which recognizes inventors' rights as sacred and inviolable property rights.

Now that we have established where our present patent systems come from, it is interesting to take a look at their particular characteristics. It has already been mentioned that patents are titles conferred by the State, so that the rights actually represent recognition by the State. They do not legally come into being until such time as the State has caused them to be recognized by means of a procedure laid down in its legislation. As a general rule the inventor applies to a public office, usually a registry, where he has to provide a clear and concise description of the invention by filing various documents accompanied, where possible, by the corresponding drawings.

The inventor has to describe the invention clearly and in detail. The description has to be sufficient for a technical person with average skill in the field to be able to carry out the invention by following the instructions given by the inventor. The fundamental part of the description is called the claims; these constitute a set of coordinates, as it were, that demarcate the scope of the invention. The claims thus serve to define the extent of the exclusive rights, as the protection is determined solely by the information that they provide.

For an invention to be eligible for patenting, it has to comply with three universally accepted requirements. They are novelty, inventive step and industrial applicability. An invention is novel if it was not known previously, in other words has not been anticipated. Two types of novelty stem from this basic concept, namely relative and universal novelty. Relative novelty has to do with the technical solution embodied in

the invention not having been previously known in a particular territory or area, while universal novelty, as its name suggests, relates to non-preexistence or non-anticipation anywhere in the world. The latter type of novelty is the most widely recognized internationally.

Inventive step is a rather more subjective criterion, and it is also known as non-obviousness, or the fact of the invention not being obvious to a person with average skill in the field concerned. Apart from being novel the invention must, in order to qualify for protection, have required a certain degree of ingenuity; it must reflect an element of creativeness, and be more than just the result of daily experience or of knowledge *per se*.

As a practical solution to a problem in industry, the invention must be useful, must possess a certain usefulness or, as some legislation puts it, it must have industrial applicability. This requirement means that the invention has to have an essential aim, it has to serve a purpose in the outside world.

All specific legislation takes care to put a different slant on the formalities to be complied with to qualify for patent rights; it lays down the conditions, criteria and forms to be met for all these requirements to be fulfilled. One thing that must be emphasized is the fact that patent systems are territorial. This shows up in the fact that the patent, like any other instrument issuing from the authorities, is effective only within the specific territory of the State that grants it. Another characteristic is that patents have only temporary validity; the protection that they afford is limited in time, the actual term being laid down in the relevant legislation. What is more, the rights acquired are entirely transferable, like all other kinds of right, by the usual means specified in civil law. Generally the only requirement imposed on transfer is publicity, for the sake of third-party legal security.

Last but not least, the rights conferred by the patent generally relate to the exclusive use, during a specific period, of the invention that forms the subject matter of the patent. Use is a generic term that has been defined by some legislation as the patent owner's right to exploit the invention exclusively, or to prohibit third parties from exploiting it without his consent. Exclusive use thus encompasses acts of manufacture, importation, placing on sale, sale, marketing, industrialization, etc., in fact any act that entails making the patented product or process available to the public.

4. Patents for Pharmaceutical Products

Obviously, as technical and industrial needs and economic organization have evolved, patent law has itself evolved in recent years. In Europe above all, where it originated, the relevant provisions went on from being a vehicle for promoting the development of local industry and became a factor of the internationalizing phenomenon that has made it possible for the owners of patents to work them at the international level.

It is thus worth noting that patent law has evolved and continues to evolve in line with the economic and technical-industrial necessities of the country in which it operates. This moreover explains the concept of industrial property in general being an instrument of development, a tool which, depending on the shape given it, is capable of influencing the economic and ultimately the social development of the country in which it is applied.

Countries have been designing the provisions of their patent laws according to their particular levels of development and specific needs. One thing does have to be superimposed on that picture, however, namely the results of various analytical exercises of an economic nature that have considered the economic effects of innovative activity. It has for instance been accepted that, while it is true that the grant of exclusive, indeed monopolistic rights in some cases makes for a short-term distortion of the economy, that is the price that a market economy has to pay if it is to have access to technological innovations. Even though there is no world consensus on whether or not patent rights should be called a monopoly, with some saying that they should and others emphatically contradicting them, one thing that is acknowledged is the effects, in economic terms, that patent provisions have in a particular economic environment. Perhaps the most widely discussed effect is the higher prices charged for patented products.

It is for these reasons that the patent protection of innovations concerned with chemical, pharmaceutical and food products has been one of the most controversial subjects in industrial property. The exclusion of chemicals from patentability occurred for the first time in history in a German law of 1877. The reasons given at the time were that it was necessary to reinvigorate an industry that was lagging behind its counterparts in other countries. Even before that, a French law of 1844 had expressly excluded pharmaceutical chemicals from patentability.

The subject of the patent protection of pharmaceutical compositions is vitally important. First it is a subject with strong social connotations: it touches on areas as sensitive as health and man's quality of life, even his survival. Secondly, the chemical and pharmaceutical industry depends to a large extent on costly research and development programs for the production of new inventions, which means that it is more necessary than in other areas of industry to be able to protect them with patents. This is compounded by the fact that chemical and pharmaceutical products are more often than not relatively easy to copy.

It is said that, once they had achieved a certain level of development of their pharmaceutical industries, the developed countries amended their legislation to extend patent protection to pharmaceutical products. What is certain is that it was not until 1960 that France introduced protection, with Germany following in 1968, Italy in 1978, and Japan and Switzerland in 1976 and 1977 respectively. Meanwhile, ironically at the same time, the majority of the developing countries, acting in response to economic policies of import substitution and to a general feeling that intellectual property protection systems were not conducive to scientific and technological development, indeed actually hampered it, took steps to exclude chemical, pharmaceutical and food products from patentability. It was argued at the time that the scientific and technological gap

separating developed from developing countries was too wide, and that patent systems were quite simply liable to widen it further. From that point of view, therefore, there were indications of a serious threat to any prospects of the right to health being guaranteed.

Since then controversy has raged within the transnational chemical and pharmaceutical industry, with support from the governments of developed and developing countries. Various kinds of argument have been put forward in the course of the debate; on the one hand there are the pharmaceutical patent's detractors, who point mainly to the increase in the price of drugs and the consequent restriction of access to them for certain sectors of the population; on the other hand it is said that the grant of protection will bring about the removal of a local industry that owes its very existence to the possibility of reproducing and marketing the innovations of the transnational pharmaceutical industry, causing an adverse balance of payments effect attributable to the encouragement of drug imports.

The defenders of drug patenting, for their part, base their reasoning on the general assumption that intellectual property protection is an inducement to scientific and technological development. The incentives that will make members of a community decide to invest in research and the development of new knowledge are constituted in the modern world by intellectual property protection. According to this argument, the patent system has shown itself to be the only efficient means of promoting research and development for the acquisition of new knowledge, which eventually brings about an improvement in social and economic well-being. Other arguments put forward are usually the promotion of technology transfer, the stimulation of direct foreign investment and the guarantee of product quality.

This paper is not the place for analyzing the two positions and establishing which is the right one; its aim is quite simply to give an objective account of the evolution of the concepts, above all when the only consensus that has been achieved is that there is no consensus. Literature is full of studies seeking to demonstrate the validity of one or other of the two positions either from a legal or from an economic standpoint; there are strong and weak arguments at both extremes, and much of the analysis is actually empirical in nature; what is certain is that the subject is a very complex one which lends itself to many different interpretations. Recently, in a World Bank-sponsored discussion on the Internet on the general subject of the appropriateness or otherwise of protecting intellectual property in developing countries, the difference of opinions was flagrant.

Even though the discussion is as animated as ever, it does seem to have been overtaken by events, above all if we consider the fact that the majority of countries have already acknowledged the idea of patenting for pharmaceutical products and processes for a period of 20 years, namely in the framework of the Uruguay Round of trade negotiations that resulted in the creation of the World Trade Organization (WTO), and specifically the adoption of the TRIPS Agreement.

After many years of arduous discussion, the developing countries endorsed the developed countries' plans to strengthen intellectual property systems by means of more extensive harmonization and standardization of criteria, the aim being to remove the distortions that can occur in international trade on account of weak intellectual property protection laws. The arguments in favor of greater and more effective protection for intellectual property rights focused on the view that, in a globalized world economy strongly biased towards free international trade, there is a need for strong protection systems capable of promoting innovation and scientific and technological development. Another point that was made had to do with the great losses that piracy inflicted on transnational companies at world level.

For the purposes of the subject of this paper, the TRIPS Agreement provides that the Members of the WTO, and therefore the signatories of the Agreement, will have to grant protection by means of patents, namely process as well as product patents, in all areas of technology, including the chemical, pharmaceutical and food sectors. Even though the Agreement does provide for certain exceptions, the sectors in question were not among them. The obligation includes the grant of protection for a period of 20 years. Other provisions have to do with the possibility of granting compulsory licenses and reversing the burden of proof in the case of processes that are alleged to have infringed process patents.

Owing to the arduous nature of the discussions, the developed countries eventually agreed to allow less advanced countries transition periods for the implementation of their obligations under the Agreement. As a result, countries that do not accord protection to chemical, pharmaceutical and food products now have until the year 2005 to bring their legislation into line with the TRIPS provisions. But even before that, the countries are under the obligation to provide in their administrative procedures for a means whereby patent applications for such inventions may be filed, those applications being subject, as from the date of implementation of the Agreement, to the patentability criteria laid down in it as if the criteria were already in operation in the country concerned on the filing date of the applications, or, if a priority date could be and actually were claimed, on the filing date of the priority application. Likewise the patent protection date is established in accordance with the Agreement, from the grant of the patent and throughout the balance of its term, as from the filing date of the application. This system has come to be known as the "mailbox" or "black box" system.

Another provision closely related to the previous one relates to the situation where, if a product is the subject of a patent application according to the procedure described, exclusive marketing rights are granted for a period of five years calculated from the time at which marketing approval is obtained in the country concerned, or until a product patent is granted or refused in that country, whichever period is shorter; this is conditional on a patent application having been filed and a patent having been granted for the product, and marketing approval having been obtained in another Member of the WTO after the date of entry into force of the TRIPS Agreement.

In spite of the entry into force of the TRIPS Agreement, the state of protection of pharmaceutical products is still not uniform throughout the world. Some countries had already amended their legislation, even before signing the Agreement. Some were compelled to do so by the risk of economic reprisals from their main trading partners, while still others acted in expectation of possible access to better and wider markets. The majority of the small, less developed countries, however, are making use of the transitional periods that the Agreement has allowed them, and have not amended their legislation. What is certain is that by the year 2005 patents for pharmaceutical products will be a reality on a world scale, and that those countries that do not grant them and are Members of the WTO will be exposed to dispute settlement procedures within the framework of the Organization, and to the corresponding economic reprisals.

One important point that should also be mentioned in closing this subject is that some developed countries, especially the United States of America, find that the provisions of the TRIPS Agreement still do not provide sufficient protection for the pharmaceutical industry. They therefore advocate a bilateral arrangement with the introduction of a retroactive system whereby, in countries where there has hitherto been no protection for pharmaceutical products and the law changes, a period of grace is allowed during which it is possible to patent products that have already been patented in other countries, but have not yet been actually marketed in those countries. This system is known as the pipeline system, and has been introduced in the legislation of a number of countries including Mexico and Brazil.

5. Parallel Imports

Another subject that is related to the patenting of pharmaceutical products, although in fact it is one that could be applied generally to all products protected by intellectual property rights, is that of parallel imports.

Any discussion of parallel imports is bound to include the matter of the exhaustion of intellectual property rights. As mentioned in earlier paragraphs, the patent system grants the owner of a patent the exclusive right to use, or work, the patent within a specific territory, and that obviously includes marketing. When exclusive rights are granted, the legislation has also to provide for the degree of control that the owner should be allowed over the marketable products protected by the intellectual property rights. It therefore has to decree whether the rights are exhausted on the first sale or whether the owner continues to enjoy the rights regardless of how many commercial transactions take place. This is particularly important in an age of booming international trade, and in practical terms serves to deal with the risk of a patented product having been legitimately introduced into a country, being potentially exportable, by a third party and not by the owner, to another country in which the third party would then also enjoy protection.

Under the provisions of the TRIPS Agreement, importation is one of the rights conferred on the owner of the patent, but it will be up to the legislation of each country to

determine the scope of those rights, as the TRIPS Agreement does not settle the matter of exhaustion.

The parallel imports question is of particular relevance to the pharmaceutical industry, being capable of weakening its position on the world market. Parallel imports can be defined as a practice in international trade whereby a distributor, without any concession or license from the owner of the patent, purchases patented products in countries where the price is low and sells them in countries where higher prices are charged, in spite of the fact that there are companies in the latter countries that have been licensed to distribute the products by the owner of the patent.

A parallel import situation therefore arises whenever the following three conditions are met: there is a patented product, there is a price difference that makes importation attractive, and there is an intermediary operating alongside the patent owner's legitimate licensee.

As the situation is one determined by price, the fact that a product is or is not patented on a given market has a bearing on that situation, as it is well known that, if patents are not granted, there is a risk of copies or imitations being produced that can be brought on to the market at lower prices due to the fact that the manufacturer does not have to recoup the high research and product development costs involved; all he has had to do is analyze the product, work out its composition and manufacture it. Where there is inequality in the levels of protection of pharmaceutical products, there are bound to be distortions owing to the possibility of the same products being brought on to the market but coming from an unauthorized third party. And then of course there are those, above all in developing countries, who regard allowing parallel imports as providing access to pharmaceutical products at prices that the people can more easily afford.

With regard to exhaustion in the national context, legal literature and legislation have consistently held that the first disposal of goods exhausts the patent rights. So, on distributing the patented goods on the market, the owner or a third party authorized by him loses control over them. This happens because it is necessary to ensure the free availability of merchandise in such a way that the owners of the intellectual property rights in particular goods do not restrict their free circulation.

The effect of the application of the exhaustion of rights principle is that the owner of the patent loses the power to prevent or limit the circulation of the protected goods once they have been sold by him or with his consent. However, the principle applies only to the rights pertaining to circulation, and to articles brought on to the market. The loss of control does not in any way empower the acquirer of the patented goods to manufacture new goods, as in that case he would still be infringing the patent.

The picture changes completely when it comes to applying the exhaustion principle in the context of international trade. There is no consensus on the approach to be adopted where the first sale of the patented product occurs abroad. Legal literature and case law have both opted for different solutions in specific cases, taking into account

the different perceptions in various parts of the world of the underlying foundation of patent protection, the different territoriality criteria and the specific conditions written into such licenses as are granted.

Finally, it has to be understood that, while the subject of parallel imports is acknowledged to be closely tied up with that of patent rights, the problem that such imports represent is not an intellectual property problem alone, because in any situation that arises out of price differentials, regardless of whether or not the products involved are patented, there need only be a sufficiently attractive difference in price for someone to contemplate taking advantage of it.

6. Access to Biological Resources

A large part of the analysis that follows, concerning the controversy that has arisen from the possibility of acquiring patents for biological material, and access to such material, is attributable to the evolution undergone by the patent system itself, which, having been a system applied to inanimate objects or processes involving inert material, has become a system applicable also to live material. It is therefore important to give an account of the way in which that evolution took place if the picture is to be properly understood.

It has to be accepted that patent systems were devised for the protection of processes and inanimate objects, and that, because the principles enshrined in them were thus intended for inert material, applying them to living organisms has been a whole new challenge for industrial property.

The United States of America (the U.S.A.) was the pioneer in the grant of protection to living organisms. In 1930, the Plant Patent Act granting protection to asexually reproduced plants was enacted. Basically, the Act introduced a special regime for this type of plant that was different from the system of utility patents prevailing in the country.

Later on, in Europe, a new system of intellectual property rights for the exclusive protection of new varieties of plants began to emerge during the 1950s. This was a *sui generis* protection system for new varieties or strains of plants. The system protected the creations of plant breeders that materialized as new plant forms.

When we discuss the possibility of patenting living organisms, notably plants, we shall be referring first to the way in which the subject evolved in certain industrialized countries. We would start by saying that, in the U.S.A., the Patent and Trademark Office traditionally considered natural products and living organisms to be products of nature and therefore not patentable. The only exception made to that rule was when certain patents were granted to Louis Pasteur in 1873; in them, recognition was given to claims of processes that involved yeasts, which for the purpose were assimilated to a manufacturing process.

Nevertheless, the Court of Appeal ruled in a 1977 case that, even though natural products *per se* could not be patented, it was possible to acquire protection for any new form or composition. So, if man were capable of isolating a natural element that did not exist as such in nature, and of giving it a function, that element was patentable. This stance led to the acceptance of purified natural products as being new and patentable. From that decision onwards, patents began to be granted for living organisms.

In 1980, the Supreme Court ruled, in the celebrated *Diamond v. Chakrabarty* case, that a patent should be granted for the first genetically modified bacterium capable of cleaning up oil slicks. The court ruled that a living, man-made microorganism had to be protected under legislation of the U.S.A. as a product or composition of matter. That decision gave the U.S.A. Patent and Trademark Office a legal framework within which to grant patents both for plants and for non-human animals. It is worth mentioning that this decision refers to a utility patent concept, in contrast to the patent concept of the Plant Patent Act which was mentioned at the beginning of this subsection.

In 1985, a patent was granted for a variety of maize that contained an increased level of the amino acid trytophane, and in 1988 the first patent was granted for a genetically altered animal, namely a rat that was given a uniform susceptibility to cancer, which made it an excellent instrument for research on possible cures for the disease.

The situation in the U.S.A. has evolved to such an extent that even human genetic material has since been patented. It is now possible in that country to patent genes, their location, the means of locating them, gene techniques, cloning techniques, diagnostic probes, etc.

In Europe, the European Patent Office granted the first patent for a microorganism in 1981, while the first patent for a plant was granted in 1989, even though the legal provisions on the subject were not clear. The patent for the "oncorat" was granted in 1992 on the ground that the modified rat did not conform to the existing provision that precluded the patenting of animals. Very recently a number of very bold provisions have been enacted on the patenting of biotechnological inventions. Briefly put, the recent European Directive provides that it is possible to patent inventions that contain biological material or processes by which biological material may be produced. It nevertheless still excludes animals, plant varieties and essentially biological processes for the production of plants and animals from patentability. Likewise excluded from patentability are the human body, at whatever stage of its formation and development, and the mere discovery of one of its elements, including gene sequences or partial gene sequences.

While one could describe the foregoing as progress, the legal protection of living organisms has been the subject of much discussion. It involves ethical, philosophical, religious and political considerations, and these have fuelled the debate on whether or not it is right to protect inventions of this kind by means of intellectual property rights. For instance, the small number of patents that have been granted for plants and animals in the

European Union have been officially opposed by a number of organizations. More than 80 non-governmental organizations collectively filed a legal objection to the grant of the patent for the oncorat. We shall consider this subject in greater detail in the section on bioethics.

Now that it has been established that it is possible to obtain industrial property protection for living organisms, it becomes important to deal with the subject of access to biological resources.

The relations between intellectual property protection and access to biological resources have been a very popular subject in recent years, its popularity being due to the fact that both issues have taken on considerable economic importance. In the first instance there are inventions, translated into scientific and technological and hence socio-economic development, and then there are natural resources, which are vital to the survival of the planet.

As with any human interest subject, it is possible to consider the relation between intellectual property rights and biological diversity from several different angles. On closer analysis, one sees that the subject is a very broad one with many different facets and therefore susceptible to many different approaches. In this section, therefore, we aim to give a general picture of what lies behind its popularity, without attempting to go to any length on account of space considerations. The general objective is to introduce the subject and set out its most important features, in an attempt to give an overall picture.

It is important to take another aspect into account, namely the fact that, when dealing with the possibility of having access to a country's biological resources, in conjunction with the possibility of using them for the production of inventions qualifying for intellectual property protection, one has to consider sensitive aspects such as life, the preservation of the environment, food resources, prospection for biological resources, health, the conservation of species, technology transfer, etc., which bring a great many highly involved ethical, legal and philosophical considerations into play.

Also, before going into greater depth on this subject, it is advisable to define just what is meant by intellectual property and what is meant by biological diversity, as both terms have been tortuously used in the discussions that have taken place on the subject.

For that reason, when it comes to the definition of the intellectual property concept, attorneys and professionals from other disciplines, such as biologists, philosophers, etc., tend not to speak the same language. The former refer to a stricter, more technical conception of intellectual property, speaking of patents, trademarks, industrial secrets and so on. The professionals from other disciplines, for their part, refer to it in a broader way as a means of protecting innovation, including by non-traditional methods, and this explains why concepts such as the rights of farmers and discoverers and the protection of traditional knowledge, among others, have arisen.

On the other hand, according to the CBD, "'Biological diversity' means 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." The term has to be contrasted with that of genetic resources, which refers more specifically to genetic material "of actual or potential value" to humanity. Genetic resources is the more suitable term when speaking of plants in the context of their genetic improvement or the manipulation of their genetic material. In the context of intellectual property the reference would thus be to patents and plant breeders' rights, or any other *sui generis* system for the protection of plant varieties, in line with the TRIPS Agreement.

Similarly, when we speak of bioprospecting, another highly fashionable term, above all in relation to the development of pharmaceutical products, we are referring to the use of biological diversity as a source of novel secondary metabolites to produce goods, which for the time being means above all pharmaceutical goods, but which could include goods of other kinds, such as perfumes. So in this context it is possible also to use the terms natural biological resources or natural products.

As we see then, even though there are certain conceptual differences, there is an inevitable interrelationship, as genetic resources are the product of biological diversity. The point that has to be made here is that, when referring to genetic resources, there is a stronger link to agriculture, whereas when referring to bioprospecting the stronger link is to the pharmaceutical industry.

These differences are important in any attempt to relate the concepts to intellectual property rights, as, depending on what is being referred to, it will be dealt with in one way or another. For instance, when speaking of access to biological resources, it is necessary to set it against a background of patenting products derived from a natural resource.

Traditionally biodiversity was considered a resource of mankind. This conception gave it the status of a common inheritance or heritage, although in fact, because it belonged to the human race, it belonged to everyone and no one, and anyone could make use of it. So free access to biological resources and germplasm was the order of the day. This was the premise, for instance, that has underlain the whole of world agricultural development, which has taken place over millennia and involved the participation of many peoples who have imparted their knowledge and culture.

As industrial property has evolved, however, and with it the possibility of affording legal protection to living organisms, thereby making it possible for the owner to secure exclusive rights in the use of the protected material, profound contradictions have begun to emerge, arising from the fact that biodiversity has become a raw material for the development of new products, and above all pharmaceutical products.

It is well known that the geographical distribution of biodiversity is very uneven, and it often happens that it is concentrated in less developed countries with little

territorial scope and limited research and development potential. It has not been said lightly that the countries of the Third World possess "green wealth," which has also been called green oil or green gold.

This is what makes for the great ironies where products developed with extracts originating in a specific country, on being transformed in laboratories in industrialized countries, become commercially valuable goods that are sold and distributed throughout the world, passing through the hands of transnational companies, without the country of origin deriving any benefit from the exercise. Cases begin to arise such as that of the red periwinkle of Madagascar, where a pharmaceutical company, using this natural resource, patented Vincristine, which is used for the treatment of leukemia in children, and earned millions for the company without Madagascar receiving any recognition at all for its involvement.

There does not seem to be a logical explanation for this state of affairs, as petroleum, for instance, which is also a natural resource, has never been considered common property, and the few countries lucky enough to have oilfields on their territory have extracted great economic rewards from the situation. So the fact that all countries have cost-free, unrestricted access to the natural resources of another country without the latter being given credit for its contribution as the provider of the biological resource is inexplicable but nonetheless a fact, like many others in this world.

The wide-ranging discussions that have taken place on the subject throughout the world, together with some resolutions of the Food and Agriculture Organization (FAO) on its repercussions in agriculture, provided background to what was negotiated and settled in 1992 at the United Nations Conference on Environment and Development in Rio de Janeiro, the result of which was the signature of the CBD by 157 countries.

The signature of this Convention stirred up great controversy and confrontation between developed countries and the Third World, owing to the fact that it's proposals radically altered the picture described earlier.

Briefly, as far as our subject is concerned, the Rio Convention was a reaffirmation of the value of genetic resources for the future of mankind, and the sovereign right of every State to its biological diversity. Clearly it has caused a complete break with the established scheme of things, in the sense that biological diversity has ceased to be freely accessible and is now a resource specific to each country.

In particular, Article 3 of the Convention provides that "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies." This provision is enlarged upon in Article 15, which empowers States to control access to the resources by legislation, opening the way to negotiations between parties for the fair and equitable sharing, (with the party providing the resources), of the results of research and development activities and the benefits deriving from commercial and any other exploitation.

It is important to point out that the Convention departs from the classical format for international treaties of its kind by including matters pertaining to trade, intellectual property and technology transfer in an environmental context.

Technology transfer, which is dealt with in Article 16, was perhaps the most hotly debated subject of the Conference. The Article establishes the importance of technology transfer to the attainment of the objectives of the Convention, including the transfer of biotechnology, and also the importance of the transfer taking place on "concessional and preferential terms" for developing countries. It further recognizes the existence of traditional and indigenous technology.

Even though what the developing countries achieved can be regarded as considerable, it is only logical to assume also that many subjects were left on the drawing-board, and that the negotiations were tough, to such an extent indeed that the U.S.A. refused to sign the Convention, arguing failure to respect intellectual property rights and possible economic prejudice to its biotechnological and especially pharmaceutical industries. The main obstacle that the companies complained of was that the Convention favored the grant of compulsory licenses, a policy to which the U.S.A. is vehemently opposed. With the change of government, however, and after a change of heart on the part of the companies, President Bill Clinton signed the CBD, although it has yet to be ratified by Congress.

When intellectual property is related to biological diversity, the first questions that arise have to do with the notion of biological and genetic resources actually being property, in other words marketable, a matter which undoubtedly involves ethical considerations. Other matters raised by this topic are the appropriation without due recognition, either moral or economic, of indigenous knowledge that has been handed down from generation to generation, the difficulty of setting a value on biological diversity, the scientific and technological gap separating developed and underdeveloped countries and the problem of identifying all those involved in the development of the product, to mention only a few. By all accounts the use of intellectual property rights for protection in this area is coming up against a barrage of criticism.

When pressed, however, underdeveloped countries see that they are faced with the great dilemma of having to have sufficient protection, as otherwise barriers will go up to deny them access to the technology of the future that is capable of bringing them their much-desired development. The very point of protecting innovation is that innovation is thereby promoted, so refusing to protect it would ultimately be worse than all the questions that arise.

In spite of the great international debate that has taken place on these issues, as we have seen, there is still no clear picture of how access to biological and genetic resources is to be controlled, or how a certain level of ownership of such resources is to be achieved. Since the entry into force of the CBD, only about ten of the 168 countries that ratified it have actually enacted laws implementing it, and almost all of those are open to

criticism, especially with respect to the practical difficulty of regulating this area of concern. Two examples are the Philippines and Costa Rica.

The practical difficulty lies in the search for a middle path between the regulation of research and development and its encouragement, so that the country may be assured of sovereignty over its biological resources and at the same time given the means of promoting and supporting innovation.

Some methods that have been used for recognizing the contribution of regions or peoples in the development of pharmaceutical products are particular types of law, like those already mentioned, and private contracts. They provide an interesting source of information on how some of the questions are being settled in the form of relatively recent specific cases in a continuously evolving field. The reservation has to be made that space precludes an actual evaluation of the good and bad features of the examples, which will be merely listed.

The first and perhaps the earliest example has to do with the Natural Products Division of the U.S.A. National Cancer Institute (NCI). The method used by the NCI is that of collection contracts, which are backed up by the so-called Collection Charter, the purpose of which is precisely to solve the problems that confront a research institute when part of its activities involve the gathering of natural products in developing countries. The Charter therefore contains provisions on matters such as the use of indigenous knowledge, technology transfer, intellectual property and conservation.

Another very interesting example is the model provided by Andes Pharmaceuticals, Inc. This company was created by professionals from various disciplines in North and South America whose sole purpose was the practical implementation of all the objectives of the CBD. In its profile, Andes states that it is committed to the equitable distribution of income, genuine transfer of technology, the promotion of sustainable development and the improvement of world health. The Andes model is highly interesting to analyze, but what we wish to point out for the time being is the intellectual property pledges that it makes. In that respect Andes has imposed on itself the objective of according the status of inventor to all parties contributing to the development of an invention, as a kind of recognition of the value of indigenous knowledge, and of compensating individuals and communities in the best way possible, even though that may entail departing from the traditional stereotypes of recognition and compensation.

Another model worth mentioning is that of the National Institute of Biodiversity of Costa Rica (InBIO). InBIO was set up as a private institution in the public interest with a view to compiling the most exhaustive inventory possible of the country's biodiversity and making a practical reality of the axiom "I know, I save and I use." The proposals of InBIO regarding Costa Rican biodiversity are based on sustainable development and on the firm conviction that Costa Rican society can reap major benefits from the conservation and rational use of its biological resources.

As part of this working scheme, InBIO signed a scientific collaboration agreement with Merck, Sharp and Dohme in 1991. In the contract, InBIO undertook to provide extracts from the Costa Rican forests to be studied for their suitability or viability as ingredients of new drugs, for which it would be paid an initial cash sum and thereafter royalties on sales should the extracts eventually be made into products and brought on to the market.

What the agreement between InBIO and Merck means for Costa Rica is a share in possible revenue, participation of the University of Costa Rica in the production of the extracts, technical cooperation in training, equipment and infrastructure, and above all international recognition for the first time, by a transnational pharmaceutical company, of the involvement of an underdeveloped country in the development of its products. The benefits for Costa Rica also included the matter of conservation, as under an agreement signed between InBIO and the Ministry of Environment and Energy a large portion of the revenue from the agreement will serve to build up national conservation programs and enhance environmental protection.

In spite of these benefits, and the fact that the debate on the contract with Merck drew attention to the systematic, totally uncontrolled stripping of the Costa Rican forests by unscrupulous operators, there was a great deal of opposition to it. InBIO had to face extensive questioning, and was accused of supposedly commercializing the national heritage. Since then, a major part of Costa Rican society has understood the motive that brought about the signing of the agreement and the benefits offered by it, and at the international level there is even general recognition and admiration. The conclusion was reached that as in any event the forests were being ruined by the clandestine tapping of their biological resources, it was better that it be done in a sustainable way, and that the country be assured of the economic benefits that it deserved. In that way the InBIO-Merck agreement eventually became a model or example to be followed by underdeveloped countries.

Undoubtedly this situation contains within itself great challenges for the future of industrial property, especially patents. The need to recognize the value of indigenous or traditional knowledge once again refocuses the inventor concept, which at the outset denoted an individual and then grew to mean a group or team. Now, for the purposes of inventions deriving from biological products, what is needed is a still-broader perception of the concept to include the recognition, in the making of the invention, of a whole series of collaborators without whose contribution the end product would never have seen the light of day.

It is also interesting to mention that, speaking of recognition, one should also be speaking of compensation, and it is there that the greatest challenges are to be found. How is compensation to be given? Should individuals or whole communities be compensated? What kind of compensation is the most appropriate? Not one of these questions has yet been given a reply on which the world has been unanimous.

Another area in which there is much work to be done concerns the framing of minimum provisions for bioprospecting contracts and contracts for the transfer of genetic material. Such contracts should conform to the new principles or models that we have mentioned.

The thing to do seems to be to strike a balance between protection, recognition and compensation for all those involved in the process, meaning countries, communities, companies and individuals. Some *sui generis* proposals put forward for the recognition of indigenous innovation have included the creation of so-called Intellectual Property Rights of the Community, affording intellectual property protection to plant genetic resources by introducing rights for farmers and plant improvers.

Other proposals advocate the use of a public defender or ombudsman to protect the rights of communities and countries, inventors' certificates, the implementation of the WIPO/UNESCO Model Provisions on Expressions of Folklore and the creation of "rights in traditional resources" involving intellectual property rights, but with a broader coverage including the recognition of human, religious, territorial and cultural rights.

Obviously these proposals raise enormous question marks, and it is precisely for that reason that they have been called major challenges: they call for a serious commitment to discussion, analysis and the drawing of conclusions that will satisfy all parties.

7. Bioethics

As a final point for this paper, and without claiming to have been exhaustive in our treatment of the subject, we shall touch on bioethics. As a set of standards that govern the life of mankind, ethics have always been present at all stages in the development of science and technology.

We have already mentioned in this article how science and technology have evolved in such a way that scientists are now capable of things that once would have been the stuff of a science fiction novel, including for instance the cloning of higher mammals. Biotechnology is the technique that consists in using live organisms to produce goods and conduct processes. It has been used since ancient times in the fermentation processes for the production of beer and cheeses, but it was not until recent times, with scientists devising the techniques of genetic engineering and thereby developing the ability to manipulate living creatures genetically, that mankind has had to face up to the most serious questions that science has presented it with.

With the discovery in 1953 of the structure of deoxyribonucleic acid (DNA) by James Watson and Francis Crick, enormous scientific expectations were entertained regarding that most intimate component of the human being, his genetic code, the genetic information or the set of hereditary characteristics of his organism that are handed down to his descendants.

Knowledge of the human genome, added to the possibility of isolating human genes, which came about in 1977, and the possibility of genetic manipulation of organisms, aroused great scientific interest in this field, with the opportunities that it offered for preventing and curing diseases that until then had been difficult to eradicate from the human race.

The genome is the assemblage of hereditary material that every living being possesses and passes on to its descendants. It consists of two filaments, each one more than a meter in length and chemically known as DNA. It is in DNA that the genetic information received from one's parents is located. The filaments are joined to each other in a spiral or double helix form in every one of the cells of an organism, and split when the cells divide in the chromosomes, of which man has 23 pairs. The filaments are made up of nucleotides, and the nucleotides in turn are made up of base pairs, numbering three billion in a human being.

The component that lends DNA it's informative property may be described as a lateral protrusion of each of the chains of the double helix, which is matched to a similar component on the other chain according to strict rules, which gives the chains the appearance of the steps on a spiral staircase constituted by the double helix shape. Given that the components constituting this sort of stairway are not equal to each other, it is in the sequence that they adopt along the length of the molecular chains that the genetic information is found. In that way, if the sequential dynamic of one of the chains is not known, it may be immediately deduced from the complementary chain.

All this gave its importance to the Human Genome Project, which started in the U.S.A. in 1990 and has since been endorsed by a large number of countries around the world. The main objective of the Human Genome Project is the identification of the approximately 80,000 genes that constitute human DNA, and the working out of the sequences of three billion chemical bases that form it, their incorporation in databases and the development of instruments to analyze them.

The Project was originally calculated to last for some 15 years, but it was announced recently that special equipment could be used to reduce that time considerably; its cost has been put at three billion dollars. It is financed for the most part with U.S.A. Government funds and is overseen by the Office of Research and Environmental Health of the Energy Department and by the National Genome Research Center of the country's National Institutes of Health. It is important to point out that the information generated in the course of the project is included in publicly available databases.

All this information means that, in practical terms, scientists are capable of diagnosing, preventing and curing diseases, even before birth, collaborating in criminal investigations, contributing to paternity research and also working in labor, insurance, marital and other environments. On the evidence, the possibilities that this conjures up seem bound to be given a favorable reception, but one thing that is certain is that the

subject of genetic diagnosis has aroused controversy owing to the sheer extent of those possibilities.

Without claiming to encompass all the questions asked, it could be said that the main concerns have ranged from the religious viewpoint, according to which man has no right to manipulate life, that being God's preserve, to more down-to-earth questions such as: Will the development of a "super race" be possible? Will mankind once again experience the horrors of the Nazi era? How is genetic information to be dealt with? Should a person be told that his or her organism is predisposed to contract a particular disease? Could an insurance company refuse insurance on the basis of genetic information? Can a genetic examination be demanded prior to marriage? Who decides what is good and bad? How far should science go?

All these questions and the obsession with finding answers to them have caused the emergence of what is called bioethics, a discipline that encompasses a set of questions with an ethical dimension, in the sense that the values and questions involved can only be settled by elective acts, made possible by the ever-greater ability of science and technology to encroach on human life.

Bioethics has also had to deal with the arguments stirred up by the possibility of patenting genes and other parts and components of the human body. As we said in earlier paragraphs, by dint of very broad interpretation of U.S.A. laws on the isolation and the function of products found in nature, it has become possible in that country to patent isolated genes, gene therapies, cloning techniques, cell lines and *ex-vivo* gene therapies that include human cells among other things, and more recently sequences of human genetic material.

By the beginning of the 1990s, the U.S.A. National Institutes of Health were already embroiled in a controversy arising from its plan to patent so-called expressed sequence tags, fragments of DNA that represent the expression of genes, without identifying the gene, so that, while it is known that the genes are from a human body, it is not known actually what gene is involved, or what its function is. The scandal reached such proportions that the NIH abandoned their plan, and indeed the Director at the time was forced to resign. In spite of the controversy, the U.S.A. Patent and Trademark Office subsequently announced that it had granted the patents to private companies. The magazine *Nature* reported that during the period between 1991 and 1995 1,175 patents were granted to 300 organizations for human gene sequences, with an average of three sequences per patent, many of them in Europe and the U.S.A., but all originating in North America and above all Japan.

To give an idea of the importance of the information to transnational pharmaceutical companies, it has been published that SmithKline invested 125 million dollars in research on the human genome for the use of its sequences in the creation of new products; Pfizer paid InCyte 425 million dollars for access to its data bank; Hoffman La Roche signed an agreement with Millennium for 470 million dollars for research on the specific genes that cause diabetes, asthma, arteriosclerosis and cancer. It

is however interesting to note for instance that, while the company SmithKline Beecham, in collaboration with Human Genome Sciences, plans to sequence, map and patent everything that it is possible to patent of the human genome; the pharmaceutical giant Merck, for its part, thinks that the human genome should not be patented. For that reason it is sponsoring a group at Washington University in St. Louis for the sequencing of the human genome and then making the information available to the public free of charge. These conflicting positions give an idea of the contentious nature of the subject.

The ethical debate going on around biotechnology is based on the fear that biotechnology has the potential for manipulating and altering the human race, and that if such things were to happen without control, they could end in the extinction of mankind. One can thus understand the emotional content of the subject and the reasoning that has induced governments and companies to set up bioethics forums. Bioethical studies attempt to strike a balance between the benefits deriving from gene therapy and genetic research and the risk of harm to individuals, society and the human race in general.

With regard to the Human Genome Project, the team of scientists working on it, grouped in an organization known by the acronym HUGO, have expressed special concern that the Project should be governed by bioethical principles. That means that the consent of the patient to the taking of samples will be crucial and, as for the information produced, most of the public will be guaranteed access to it. As far as patenting is concerned, the main worry of the members of HUGO is that the patents granted may prevent them from achieving their objective of mapping the human genome. In a public statement, HUGO expressed concern that the partial patenting of DNA sequences without identification would benefit the scientists who made routine discoveries, but penalize those who ascertained biological function or application. A strategy of that type would hamper the development of therapeutic and diagnostic methods, which was clearly not in the public interest. For their part, they promised early disclosure of information on the genome with a view to speeding up its dissemination and thereby promoting research on the functional aspects of genes.

It can thus be seen that the key discussion in this case has to do with the lack of functionality at the time of patenting the gene, sequence or cell line. That has been one of the severest criticisms of many of the patents that have been granted, as it amounts to obviating, or more accurately broadening, the criterion of the industrial applicability or usefulness of the invention.

Whether or not the patenting of gene therapy and genetic research is going to benefit society will depend on an analysis of the pros and cons traditionally associated with patenting in general, which it might be useful to summarize at this point:

<u>Arguments in Favor</u>

- Patents promote innovation and dissemination of innovation.
- Patents provide a means of licensing technology at all levels.

<u>Arguments Against</u>

- The owner of the patent may abuse his exclusive position on the market.
- Patents are prohibitively expensive for developing countries.

- Patents are a means whereby the investor can recover his investment, and without which he would not invest.
- Patents tend to go only to technology that has commercial value.
- Patents are obtained only in areas where the law permits them, and are therefore controlled by the State.
- Patenting is costly, and therefore promotes the protection of marketable technology only.
- Patents promote the secrecy of information.
- Patents delay the publication of information that is of value to health.
- Patents may preclude an indigenous community that contributed to the development of an invention from using it.
- Patents reward the rich and penalize the poor, as their main effect is to raise prices.

In addition to the above considerations there are those of ethical, philosophical and religious character, which in many cases are stronger than the economic ones. It would have to be established whether the benefits to society in terms of improved human and animal health care, food safety, environmental protection and so on are greater than the concerns expressed. What one should not lose sight of however is the human rights aspect. Obviously, from an ethical point of view, no person, corporation, organization or society should be granted exclusive rights in parts of the human body or in a clone of a human being. There are no benefits that would justify waiving such restrictions.

It was precisely in response to an urge to intervene in this discussion and with a view to establishing firm foundations for these ethical considerations that the United Nations, mainly through one of its agencies, UNESCO, has for a number of years been working on a declaration that aims to reinsure the rights and liberties of every individual within a society in the event of action on the human genome. Human dignity has to prevail over any scientific interest.

The Declaration, which has been discussed in draft form and revised for a number of years, provides that its underlying principles are recognition of the inherent dignity and inalienable right to equality of all members of the human family.

It also contains seven chapters that touch on subjects like research on the human genome, the rights of the persons involved in that research, the conditions governing the conduct of scientific activity and the duty of States to show solidarity towards individuals, families and population groups who are vulnerable to genetic diseases. It also commits States to fostering the international dissemination of scientific knowledge on the genome, and international scientific cooperation on the subject between industrialized and developing countries.

The Declaration was unanimously approved by the UNESCO General Conference in November 1997, and was described as a UNESCO contribution to the celebration of the Fiftieth Anniversary of the UDHR in 1998. All the provisions of the Declaration are relevant and interesting, but the following in particular should be highlighted.

As mentioned, the Declaration starts with the premise that the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

In another area of concern, it provides that the human genome in its natural state should not be a source of financial gain. Neither should any research on the human genome, in particular in biology, genetics and medicine, prevail over respect for the human rights, basic freedoms and human dignity of individuals or groups of people. Consequently practices contrary to human dignity, such as the cloning of human beings, should not be permitted.

Finally there are two stipulations closely related to intellectual property protection, namely that benefits from advances in biology, genetics and medicine concerning the human genome should be made available to all, with due regard for the dignity and human rights of each individual, and that the freedom of research, which is necessary for the advancement of knowledge, is part of freedom of thought. Research on the human genome must seek to offer relief from suffering and to improve the health of individuals and humankind as a whole.

8. Conclusions

Throughout man's history, the relations between the concepts of intellectual property protection and the right to health have caused serious controversy, but in one way or another these have been overcome by the signature, in the international field, of international agreements that have shed light on the discussions or provided what was more often than not a pragmatic solution to them.

Regrettably, the gap between developed and developing countries is a variable concept that is present in all discussions. Mankind as a race seems to have had difficulty in acknowledging that, as long as there is injustice, hunger, disease and pollution in the world, one cannot speak of the dignity of mankind.

There is therefore an obligation on all human beings, and especially, in this context, on those engaged in the study of intellectual property, to give its human dimension to the discipline that we are developing, duly mindful of the fact that intellectual property is not an end but a means to an end, and that ultimately what we all have to achieve is the development of mankind as a whole, without discrimination of any kind, this being indeed the aim pursued by the Universal Declaration of Human Rights.

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