

Plants genetic manipulation: an approach from intellectual property

Anisley Negrin Ruiz^{1, 2,3}, Lazaro Pino Rivero⁴

¹Department of Civil Law, Law Faculty, Central University of Las Villas (CULV), Santa Clara, 54830, Cuba, ²National Copyright Center, CULV, Santa Clara, 54830, Cuba, ³Cuban Industrial Property Office, CULV, Santa Clara, 54830, Cuba,

⁴Department of Physical-Chemistry, Faculty of Chemistry and Pharmacy, CULV, Santa Clara, 54830, Cuba

TABLE OF CONTENTS

1. Abstract
2. Introduction
3. Plants genetic modification: points of view
4. Principles to keep in mind around the risk-benefit dichotomies
5. Viability of Intellectual Property systems in order to protection of plants genome
6. Terminological differences on the field of Intellectual Property
7. Patentability scope and plants genome protection
8. International protection frame for biotechnological patents
9. Intellectual property and genetic modification of the plants in Cuba
- 9.1. Bio-security, Ethics and Bioethics
- 9.2. Regulatory national frame
10. Conclusions
11. Acknowledgements
12. References

1. ABSTRACT

From the end of the 20th century the Biotechnology has experimented a vertiginous advance so far, putting on approval concepts like bio-security and bioethics; becoming this way, the work with the genome of the plants, in a matter is worthy to be reconsidered by the juridical mark that regulates it, in order to moderate the norm to the new scientific context. The Intellectual Property, when recognizing patent rights on products that have incorporate biological material, as well as to the obtainer about the new vegetable varieties obtained, could mean an obstacle that impedes or hinder the access from the society to that product or that variety. In the same way is worthy of consideration, the fact that such products or varieties can be a risk for the human health or the Environment, and a monopoly of commercial exploitation for the holder of the patent or of the obtainer certificate. This study is about this topic; and valuation about aspects of Biotechnology related with the genome of the plants and their juridical protection, in the international sand as well in Cuba.

2. INTRODUCTION

In times of climatic changes, the modern Biotechnology, mainly the one related with the innovation about the genome of the plants in the environment of the agriculture, is presented like an alternative. Questionable, if we keep in mind the low probability of knowing the long term effects of this innovation and the impact in agricultural ecosystems. With the result that the number of followers of the "biotechnical agriculture" it is comparable to their detractors.

In such a sense, have been claimed that: "One of the reasons for those that a lot of people worry about the topic of the biotechnical agriculture is the supposition, in some circles, that approximately any production of a cultivation or control of a plague can be resolved through the genetic modification. To make it simple, the genes are the destination; work the correct genes and any problem will disappear, or at least it will be made much easier of managing. This idea rests in a dangerous lack of knowledge on what happens in the agricultural ecosystems and one of

Plants genetic manipulation

the reasons constitutes for which the Biotechnology worries a lot of people (1).

To this is added the fact that the Intellectual Property recognizes equivalent rights to a patent, to the obtainer of new varieties of plants, to which it could have been arrived for the way of the genetic manipulation. Being instituted this Certificate of Vegetable Obtaining as a monopoly of exploitation of rights for the whole time that the legislations foresee. Then, if the genetic modification of the plants, applied fundamentally to the agriculture, constitutes an alternative truly, why to recognize rights to the obtainer that impede to the society the free consumption?, and if - on the contrary -, does it constitute a danger, why to protect it?

This study is centered, then, in investigating the impact of the regimens or systems of Intellectual Property in the work with the genome of the plants, in order to promote certain academic and practical synergy, through the concrete case of Cuba.

3. PLANTS GENETIC MODIFICATION: POINTS OF VIEW

The Biotechnology, as well as the plants obtained by the obtainer of new vegetable varieties, has become topic of interest for the Intellectual Property from principles of the 20th century, although some time ago they were granting patents on inventions that involved the use of living organisms or biological material; mainly in Europe and United States of America.

By now, they are center of investigators' attention and jurists questions as: the impact of the exclusive systems of Intellectual Property in the investigation and the development related with the genome of the plants; the ethical, legal and social implications of to patent and to license in the mark of the genomic investigations; the public trust and the commercialization of these investigations; the models of property, control and co-partnership for the equal use of these investigations; as well as the relationship of the Intellectual Property with the human rights and the sanitary authorities (2-7).

It is certainly that the application of technical of the Genetic Engineering in the environment of the agriculture has generated a debate around the advantages and the risks of the plants modified genetically, as much for the human health as for the environment. For example, it has for advantage the fact of achieving via genetic modification, more resistant cultivations to herbicides, illnesses and plagues; in that way it can be avoid the use of insecticides that produce problems of environmental nature, at the time of avoiding that these virus, mushrooms and insects become more resistant every day. It also constitutes an advantage achieving more resistant cultivations to soil adverse factors and the weather like heat, freezes, droughts, salinity or acidity. As well it is the improvement of the nutritious quality and the aspect of the fruits, endowing them of a balanced nutritional content and a better flavor and texture.

The molecular agriculture could also be understood as an advantage, as "the application of the Genetic Engineering in animals and plants for drug's production, industrial chemical compounds, fuels, plastics, medical products and other materials (8).

And at the same time of the molecular agriculture is the phyto-remediation, or "application of certain plants for the regeneration of polluted soils" (8), as well the author defines it. And, although the investigations in this aspect are incipient, it has been possible to isolate certain devouring bacteria of pollutants. Anyway, the powers of degradation of these microorganisms are very specific, for what the Genetic Engineering has a decisive paper in the combination of these decontaminants, to obtain definitive results.

But as the genetic modification of the plants locks advantages mainly in the agricultural sphere, it also involves risks, as much for the environment as for the human health. Inside the first ones it is necessary to highlight the uncontrollable dispersion of the descendant of the transgenic plant and the genetic contamination from plants modified genetically toward others that have not been. The concern is centered, fundamentally in that the resistance gene is transferred to herbicide, being created equally resistant weeds.

Another important risk to keep in mind resides in the resistance to the plants modified genetically on the part of the external agents that are wanted to control as weeds, insects, virus and mushrooms. What we would be speaking of is a natural investment of the technique.

Neither the risk should be underestimated for the biological diversity. The Genetic Engineering allows selecting the qualities that are wanted in a plant, and starting from it to create a limitless number of plants whose genomes are identical to each other. The cultivation of these plants in some authors' opinion will lead to the genetic uniformity of the crops, with the rising deterioration of the biological diversity and vulnerability to illnesses, plagues or adverse factors of the soil and of the climate that it would suppose.

Now, with respect to the human health the risks of the use of the Genetic Engineering have been valued in the alimentary sector. Understanding each other for foods obtained by genetic manipulation, "those organisms that can be used as food and they have been subjected to Genetic Engineering, those that contain a derived ingredient of an organism modified genetically or those that have taken place using enzymes or other similar products in their processing" (9-17).

From these results it is spoken about the allergy cause of these foods. Being centered the risk, mostly in the fact that incorporates genetically to the food modified an allergy causing organism. In this case, the consumer would be harmed if is not informed appropriately in the labels the composition of the food. And, besides it is spoken of an allergy effect, it is spoken of a toxicity of some of these foods.

Plants genetic manipulation

Another worthy question of standing out regarding the risks to the human health is the communication to the resident bacteria in the human being, of the resistance to the antibiotics. The concern resides, in spite of any study that can demonstrate it in that the resistance passes to bacteria of the human organism, becoming us invulnerable to certain antibiotics.

4. PRINCIPLES TO KEEP IN MIND AROUND THE RISK-BENEFIT DICHOTOMIES

The search of the appropriate balance among the possible risks and benefits of the organisms modified genetically, in order to avoiding any dangerous effect on the human health or in the environment, forces to appeal to the implementation of certain relative principles to the conservation and the sustainable use. Such it is the case of the "principle of caution" and of the "principle of development."

As Bio-safety Cartagena Protocol affirms, the precaution concept recognize that determination of the acceptable risk level corresponds to scientists, establishing expressly that "lack of scientist knowledge or scientist consensus won't be understood necessarily like indicators of a such risk level, absence of risk or acceptable risk existence" (9-17).

Therefore, this principle involves in a decision to be lobbied when scientific information is not enough, non conclusive or uncertain, and when there are indications of possible effects over environment and vegetable, animal or human health can be potentially dangerous and non compatible with the protection level chosen (18-22).

It was at the United Nations Conference about environment and development, celebrated on Río de Janeiro, 1992, when this principle stay consecrate, and when take on the duty of the signatory countries to apply it when could be danger of serious or irreversible damages to the environment. However, recently, in the Bio-security Cartagena Protocol, January 2000, where keep confirmed the real role of this principle, in the modern Biotechnology field. This Protocol, which principal objective is that movement of organisms genetically modified from one country to another has made on safety terms to the environment, and human health, bring in this principle on its articles 10.6 y 11.8, letting to the importer part to decide if the importation will be made under certain conditions or not, as well as to forbid the importation, asking for additional information or delay that decision; facing the lack of scientific knowledge about genetic modification of a living organism effects to human health or environment, and in order to avoid or reduce that adverse effects (9-17).

Even so, on many countries and contexts other principles are considered pertinent, and these are more accepted every time as well on law and forming part of Biotechnology and Intellectual Property policies. Among these, we can find the "sustainable development". Countries in development ways, mostly Latin America, affirms that is not possible to apply the precaution principle

as an unbreakable rule, but it must be analyzed on conjunction with other options, where also came to play its role the education, information, recycling, non polluting production, rights management and adaptation management (18-22).

5. VIABILITY OF INTELLECTUAL PROPERTY SYSTEMS IN ORDER TO PROTECTION OF PLANTS GENOME.

Genetic Engineer, with its new modification techniques, has allowed introducing new characteristics on living organisms, but is still subject of discussion the possibility of patenting the modification results.

The United States law allows patenting all kind of modified living organism, such as microorganisms, plants or animals (not human). Meanwhile, Europe is considering a proposition made by the European Committee, for a new directive of the Council, in order to support the foundation of these rights in every country of the Union.

On the other hand, The European Council, which took place on Stockholm, on March of 2001, the biotechnological sector was identified as one of most dynamic related with economic development and employment. The biotechnological inventions, indeed, are rising, thanks to the discovery of new techniques which offers hopes in the therapeutic and alimentary fields. On this context, the European legislator considered the need to joint such development with the realization of a safety legal system, in order to allow to European companies and enterprises to develop itself and its products, which will be commercialized, as well as procedures coming from Genetic Engineer. The Directive 98/44/CE, related to legal protection of biotechnological inventions, which was adopted after a ten long years discussion in the middle of the European Council and Parliament, is an important part of that system.

In fact, the Directive settles the difference between vegetables or animal capable to be patented, and varieties of plants and animals kinds which are not. The motive of this distinction is on the ways by these animals or plants are obtained. Biological procedures are mostly the way, traditional way; meanwhile transgenic animals and plants are the result of Genetic Engineer non biological procedures.

On plants case, the Directive keeps in mind that new varieties of plant are not capable to be patented, but these are protected by Obtainers Certify. On that way, is not allowed the patent granting about a new variety of plant, but it is allowed when the inventive activity of an industrial invention is not limited to a certain vegetable variety. That's why genetic modification of a certain vegetable variety cannot be patent's object, but a superior modification, of a certain specie—for example—, can be protected by an invention's patent.

Patent laws, specifically, offers legal protection to inventions which have proved to be new, non obvious,

Plants genetic manipulation

useful and capable to be multiplied. Granting of a patent gives to its owner the civil right to inhibit to other people the commercial use of the object of the patent; excepting the use for scientific researching. In fact, the owner cannot exploit the patent by itself, and is not recognized by law as the proprietor of the materials protected by this patent.

Nowadays, the countries with a superior numbers of patents about plants are United States of America, Europe and Japan. 1930 American Patent Law deals only with plants spread out by asexual way, and around 6.500 patents about this kind of plants have been granted, roses and fruits mostly. Further it was legal established the possibility of granting utility models patents to other kinds of plants; for example, to those which have been genetically modified.

On Europe, by the way, was estimated at the beginning that patent rights was not appropriate to giving protection to new varieties of plants, developed by cultivation's traditional methods. That's why at 60's, there were established special laws on many countries to regulate breeders rights; also called Plant Diversity Rights (PDR); as well as International Convention for the Protection of New Varieties of plants (UPOV), of 1961, is the rector institution at international level. In order to avoid a legal confusion, European patent laws took off the possibility of vegetable varieties patenting.

UPOV Convention was checked on 1991, and today is not an obstacle for a double protection, by PDR or patent. This checking waits to be ratified by its Members; that's why it's not available yet.

Breeders' rights have had a great success on its own area. However, 'round these days, legal experts recognize that patent rights are better for the protection of recombining methods to produce transgenic plants and its resulting products.

The principal objective of patent systems is to promote technical innovation, essential source for economic growth, through compensations to inventors by his intellectual efforts. This way, inventions on investigation and development field are guaranteed; as well as the commercial exploitations of its results. At the same time, those patents systems promote a fast diffusion of knowledge on every related sector; without that protection, the knowledge will ever keep in secret. Patent protection, adapted to the modern biotechnology norms, can be considered an important question.

6. TERMINOLOGICAL DIFFERENCES ON THE FIELD OF INTELLECTUAL PROPERTY

For a deep analysis, is necessary to distinguish between "vegetable variety deposit", "new variety of plants protection" and "living organisms and natural procedures patents". About that, is necessarily to start saying that Intellectual Property rights was born of the protection need against unfair use of the competitor, who try to get vegetable obtaining of other obtainer, by non loyal ways.

A vegetable variety can be, as it was said before, comparable to an industrial invention, which needs on its creation an original intellectual contribution or new, according to patenting requirements, as well as an appropriate technique and systems of conservation and commercial production. Therefore, for the registry is necessarily the obtainer indicates such system of conservation on a sufficient and complete way. Thus, the improver must describe the conservation system of the new variety, naming it as "improvement of conservation".

Obtainer rights are based on covering the new vegetable variety resulting from phyto-remediation, as long as fulfill the novelty requirement, and be distinguishable, stable and uniform. The novelty required for these varieties or vegetable obtaining for its protection, show to be connected to the condition for the new variety of have not been commercialized or offered for sale by the phyto-remediation, on the asking country. Is also required that one or more of its characteristics be clearly distinguishable from other commonly known. At the same time, it has been established that this new varieties must to sustain those essentials characteristics stable for a long time after repeated spreading. That signal is named stability and/or homogeneity.

The Registry of Commercial Varieties institution was born on the second half of the past century, when agriculture was an advanced economic branch, and it was made as a "legal relationship of commercial varieties, which are settling a certain region" (23). That can be achieved by the grant of vegetable obtaining patents; but only if these obtaining are considered as industrial products. But when the question is about the living organisms patenting, the matter turns complicated, because there are not consensus yet about it.

For example, the European legislation, which is based on European Patent Convention, for patentability matters, forbid the patent granting about varieties of plants; meanwhile, Protection of Vegetable Obtaining Law, based on UPOV, allow the protection of vegetable varieties and, even when it cares about non mention of the term "patent", this law confers rights similar to varieties patents. On the other hand, laws like American's accept as valid both possibilities: the vegetable variety protection and the patent.

Distinction between both terms is located at avoiding the troubles derived of "variety patent" and "protection of obtainer of a new variety of plant's rights". Actually, this protection could be considered kindred to that which patent offers; even though these terms are different on some legal aspects. The discussion around this theme turns around how to put away those terms from protectionism that they are sought to impute; being as Intellectual Property role answer to encourage the inventive and researching through economic compensations coherent with inventors and obtainers intellectual effort. Thence, both terms go around "intangible property" of procedures and structures which stimulate the intellectual work in self.

7. PATENTABILITY SCOPE AND PLANTS GENOME PROTECTION

Arriving to this point, it can be said that new inventions, which imply an inventive activity and which have incorporated industrial applicability, even when it were about a certain product composed by biological material, or about a procedure that allows to produce, deal with or to use biological material, can be protected by patent rights. As same it is the inventions related to plants, if its technical practicality is not limited to a certain vegetable variety. Of what is deduced that will be patented, even the obtaining procedures, as well as genetically modified plants.

Then, the reach of patent protection which object was biological material with a certain characteristics, is extended to every biological material obtained from this other, by similar or different ways, but provided with the same properties. In the same way that the protection offered by a patent of a product which contains genetic information, or which it was that genetic information, is extended to every matter the product have been incorporated, or where that information has been incorporated or expressed.

About the chance of patenting plants genome, specifically, most of the scientists agree with the idea of inventive activity does not take place with the only isolation of one gene; because today that gene is obtained in an automated way, by procedures already known and generalized. Even when might be the used method deserve protection. That's if this method has the required novelty. Nevertheless, the discovery of biological function of a gene proceeds from an inventive activity which could be protection deserver. That happens when, for example, the sequence of the gene is already known and it can be use for free or not for other different function of that for what the gene was cloned in the beginning. In it would reside their utility. Remember that inventive activity is based on the utility of the patented object. On that case, a product patent can be requested. But, actually, the inventive activity found on that gene can have many reproductions, roles, etcetera; which can stay at the edge of its main utility.

United States of America has developed a jurisprudential mainstream tending to grant permission for unchecked patent about genome sequences, through the elimination or simplification of the patentability requirements asked for industrial inventions. That practice could be sustained by the economic component which is implied on the patent. This policy constitute a questionable issue, in the sense of governmental recognizing of an exclusive exploitation right, as it is the patent right, to a natural or juridical person, over genome sequences show to be connected to the constitution of exploitation monopolies over life itself. As authors stated: "If we now, according to economic interests, see us rolled on a unchecked patenting policy, without the necessarily consideration of scientific and technological real contribution, patent laws, more than increase researching, will become on an obstacle for that" (24).

8. INTERNATIONAL PROTECTION FRAME FOR BIOTECHNOLOGICAL PATENTS

As the 1961 UPOV —1991 last check still active— as Unification of Certain Elements of Invention Patents Right Convention (Strasbourg Convention), from 1963, sets the rules of legislative homogenization imposed itself about this theme for the signatory members of both international treaties. UPOV establish the principles for vegetable varieties protection through "obtainer rights". The 1991 modifications provides the strengthening of vegetable varieties obtainers rights over multiplying, commercializing, exporting and importing of the material to spread, including improvements to the potential protection of every genders and species of plants. These arrangements were incorporated to Vegetable Varieties Rights of European Union on 1995.

UPOV also introduce the "essentially derivative variety" concept, in order to allow to improve to control the use of random mutations, understanding by this varieties those which are "predominantly derivative from an initial variety or from a derivative variety of a predominantly derivative one, which still contains the genotype essential characteristics or a combination of genotypes from the initial variety" (25).

This way, the obtainer's rights stay covered. In other case, it would lose its Intellectual Property value on a shorter time. Other UPOV clauses recognizes the farmer right to preserve the seeds for the next sowing cycle, no need to ask for permission; or what is the same, "small farmer" have not to pay royalties for, and they can keep certain varieties around seven years. But, beside the flexibility, UPOV 1991's checking, came closer the obtainer rights regime to patent system. And, even when these 1991 Act's rules allow using protected varieties for researching, any improve obtained must to have significant changes on its phenotype to be considered as a "novel" variety and going to be first obtainer property. Moreover, using allowed before stays restricted now, for example: the accumulation and reproduction of protected varieties on "gene banks" guided to preserve the genetic diversity. Lastly, the farmer privilege to preserve the seed for their further sowings is removed.

Most of national patent laws of these international treaties signatory countries were emitted around the end of '70s and the beginning of '80s, as a consequence of internal adaptation of international rules of the Granting European Patent Convention (EPC) and European Patent for Common Market Convention (CPC), active both of them since 1973. That's why European Economic Community is considered as a leader on biotechnological patent issue. Respect to this, as EPC as CPC, are based on protection principles established by UPOV and Strasbourg. Those European treaties were implemented neither taking on consideration the fact of there were a 10 years difference between signature of one and others, nor technological advances on biotechnological field. With the result of EPC leaves out its patent protection vegetable varieties, as well as essentially biological

Plants genetic manipulation

procedures on the plant's production; at the same time it's allowed to patent microbiological procedures and products obtained through these methods. Even though, we must keep in mind that this Convention is not compulsory for its members. Anyway, is remarkable the fact of that European rule is claiming for an actualization, according to actual Biotechnology situation.

Such actualization seems to be materialized on the Directive 98/44/CE, related to legal protection of biotechnological inventions, which is tending to harmonize national patents laws with the ECP and communal rules about vegetable obtaining. On that way, the Directive gives the chance of patenting vegetable obtaining and biotechnological procedures, including genetically modified plants obtaining procedures.

This matter constitutes a real innovation. The motives that could carry on the European legislator to consider the patent system for Biotechnology as a benefit might be:

- The importance of biotechnological obtaining protection for industrial development of European Community.
- The number of risky inversions claimed by research and development on Genetic Engineer field, which only can be successful through the right legal protection.
- An effective and harmonized legal regulation which support and impel the inversion to make on biotechnological branch.
- The promotion of international mechanisms which guarantee the diffusion of these technologies on Third World, for more affected population benefits.

In spite of it, the Directive 98/44/CE has promoted an algid controversy about patentability of genome sequences or parts of it. Because the rule gives the chance of patenting it according the same requirement claimed to any invention solicitude on any other technology field undistinguishing between one and others: worldwide novelty, inventive activity and industrial applicability.

Those who are recognized as detractors of this norm, affirm that a mere sequence of the genome cannot be considered an industrial invention, because it doesn't fulfill the requirement of the industrial applicability, which could be defined as the capacity of the invention to be executable, and it is when, making the operations described the invention, the foreseen result is obtained (26).

On this particular case, the authors stated that: "In case it settles down a genetic sequence or a genetic partial sequence for the protection of a protein, or of a partial protein, it will be necessary what protein, or what partial protein takes place, or what function it carries out; with object of respecting the approach of the industrial application" (23).

Now, on vegetable inventions the Directive one 98/44/CE establishes that they will be patentable, whenever the application of the invention is not limited technically to

a vegetable variety. And for "vegetable variety" it has the same concept that UPOV toasts it has more than enough vegetable obtaining, expert as that variety that is characterized by the entirety of its genome, having individuality therefore to be differentiated clearly of other vegetable obtaining (23).

Of its derived it that a vegetable group, characterized by the presence of a certain gene, not for the entirety of their genome, it won't be object of the protection of varieties, therefore it won't be patentable; as neither will be it, when the invention is limited to modify a vegetable variety genetically, still when this modification is the result of a biotechnical procedure.

In consequence, in the field of exploitation of the vegetable new characteristics, Genetic Engineering result, it will be guaranteed in the States members of this Directive, previous payment of an obligation, the access in form of obligatory license when, according to the gender or the species that it is, the vegetable variety represents a technical progress, with an interest economic notable regarding the investment claimed by the patent.

Summarizing, the normative dispositions of the Directive one 98/44/CE adapt in a systematic way, the rules of the right of patents to the field of the Biotechnology, with the purpose of providing to the biotechnical inventions a level of equivalent protection in all the states members. Also, the Directive one contains a series of definitions and interpretation rules that pursue to specify what is patentable and what not; as well as the solution of conflicts regarding the demarcation with the right of vegetable obtaining.

Besides it, Directive contains norms that compel to the offices national inspectors, to follow a politics of uniform concession; as well as to the production of national equally uniform norms, mainly in what concerns to inventions whose commercial exploitation would be contrary to the public order or to the good customs.

Another international norm to keep in mind, in connection to Biosciences is the Trade-Related Aspects of Intellectual Property Rights (TRIPS); which refers to, but it is not limited to: Biotechnology, Genomics, Proteomics, Drug Discovery or even Bioinformatics (27-29), administered by the World Trade Organization (WTO) from 1994. The same allow for protection for patents for products and procedures that are given in any environment of the technology, without mediating distinction some among biotechnical patents and those that are not it.

An important question is the fact that TRIPS leaves to discretion of the States members of WTO the exclusion or not of the protection for patents of those inventions whose commercial exploitation becomes precise to impede for questions of public order and morality, protection of the health or the life of people and animals, preservation of vegetables and preservation of the environment, fundamentally. Aspect this, that has been introduced in the national legislations of the States members, in more or smaller pronouncement grade. The

Plants genetic manipulation

Directive 98/44/CE also consider non patentable the invention which commercial exploitation was against public order and morality. That's why tribunals of justice application have not the chance to do wrong or deficient interpretation of the norms. Therefore, national authorities of the signatory Countries, are the most indicated to decide if a biotechnological invention is valid, keeping on mind ethical, sociological and philosophic context, of every country.

The WTO in the TRIPS agreements, it has established approaches regarding the possibility of granting intellectual protection to the biotechnical innovations. According to the article 27.3 (b) of TRIPS, they are object of patents the plants differentiable of the micro organisms, as well as the essentially biological processes for the plant production, different from non biological processes and biological micro.

Nevertheless, these agreements TRIPS also specifies that the countries members will be able to grant intellectual protection to owners of plants by means of patents, *sui generis* systems, or a combination of both and that such dispositions will be revised four years before the entrance in vigor of the dispositions of WTO in the matter.

The article 27.3 (b) are one of the most controversial, since, on one hand it describes the patentable matters and, for the other one, it forces to the countries signatories of these agreements to protect microorganisms and certain biological processes. Reflective the above-mentioned the strong conflict of interests among the developed countries interested in obtaining protection for their biotechnical innovations, the differences among several countries about the reaches of the protection and the concern of the countries in development on the patents in ways of life.

9. INTELLECTUAL PROPERTY AND GENETIC MODIFICATION OF THE PLANTS IN CUBA.

Although the biotechnical work in Cuba finds its origins in date previous to the '80 decade, it is not until that moment that the Cuban government decides to accelerate the advance in the field of the Biotechnology, to guarantee this way the incorporation from Cuba to the world tendency of fomenting an industry of added high value products. Being developed in this way the pharmaceutical and agricultural industry.

In the agricultural sector, specifically, the Biotechnology is used under the premise that the derived benefits of that use can arrive to all, being worked in the production of seeds, cloning of plants, genetic improvement and transgenic plants; always keeping in mind the environmental impact. The incidence of the Biotechnology in the environmental sector related with the supervision of the environmental contamination and the decontamination of the Environment; as well as with the development of biological processes where they take advantage the possibilities of the organisms in the

transformation of the waste. As an example of this we have the worm composting and the bio-remediation.

9.1. Bio-security, ethics and bioethics

With the own development of the Biotechnology arises the necessity of creating norms and mechanisms able to impede and to control the impact and the negative effects of the investigation production, liberation and introduction of new species and products genetically modified, elaborated by the Biotechnology, which can attempt about the integrity of environmental, technological, socioeconomic and cultural aspects, also on the alimentary security and the quality of today's human being's life and tomorrow.

The classification Cuban juridical establish a regulatory specific mark that guarantees that the products obtained by means of use of the new techniques are as safe and innocuous as those coming from the traditional Biotechnology. Nevertheless, a project of Ordinance-law is gestating, which is in approval phase, on the Protection of the Vegetable Varieties, specifically.

Now, to the Bio-security they are associated concepts like "risk", "benefit", "effectiveness", "dissemination or dispersion"; as well as the environmental "effect of the transgenic organisms". And for the analysis of the risks of the derived products of the modern Biotechnology, we should be kept in mind the ethical values and the alternative forms in the technological development that we can take to the same result. Speaking of Bioethics we should remit ourselves to Van Rensselaer Potter, Biochemical of the University of Michigan, who in 1970 it used the term to define an ethics of the Biology and the medical practice in the clinical tests that should take the medications. Bioethics can be defined at the moment as the "analysis of the ethical matters arisen in the Biology and the Medicine, especially those taken place by the human activity in the Society and it sets him/her through the Biotechnology" (30); being also known as the ethics of the Bio-security. Therefore, an ethical behavior in Bio-security should it turns according to the economic sector in that the applications of the Biotechnology act.

9.2. Regulatory national frame

In our country it has been carried out significant inventions *in pro* of the technological development for the obtaining of organisms modified genetically (be these plants or animals) from the 80's. Being established the Center of Genetic Engineering and Biotechnology (CGEB) of Havana City, like national leader in the development of this technology, jointly with their offices in Camagüey (CGEB-C) and Sancti Spíritus (CGEB-SS). To the attainment of the same end, other institutions like the Center of Bioplants have been added, of Ciego de Ávila (CBCA), and the Biotechnology of the Plants Institute (BPI), of Villa Clara.

The studies carried out on the appreciation by the Cuban society of the transgenic foods have thrown as a result that most of people that affirm to possess knowledge on the topic sustain opinions in favor of the consumption of

Table 1. Some Cuban leading projects on biotechnology

Food	What is modificaci3n for?	Leader Center (rights owner)
Sweet potato (<i>Ipomoea batatas</i>)	Insect resistance	CIGB and CIGB Camagüey
Coffe	Insect resistance	IBP and CIGB
Sugar Cane	Fungus resistance Glufosinato tolerance	CIGB
	Glufosinato tolerance	CIGB
	Insect resistance	CIGB
	Insect resistance Glufosinato tolerance	CIGB
	FOS production	CIGB
Citrics	Fungus resistance Glufosinato tolerance	Bioplants Center and CIGB
	Virus resistance	Bioplants Center and CIGB
Corn	Insect resistance Glufosinato tolerance	CIGB
Rice	Fungus resistance Glufosinato tolerance	CIGB and CIGB Sancti Spíritus
	Insect resistance Glufosinato tolerance	CIGB and CIGB Sancti Spíritus
Banana	Fungus resistance Glufosinato tolerance	IBP y CIGB
Potato	Fungus resistance Virus resistance	CIGB
Pineapple	Insect resistance Glufosinato tolerance	Bioplants Center y CIGB
	Virus resistance Glufosinato tolerance	Bioplants Centro and CIGB
Papaya (<i>Carica papaya</i>)	Virus resistance Glufosinato tolerance	IBP and CIGB
Tilapia or St. Peter's fish	Quick growing	CIGB

the same ones. Between the projects, it has more than enough transgenic foods that are developed in Cuba we can mention those included in the Table 1 (30). Nevertheless, so far it has not been liberated, for their production generalized in the national territory, any organism modified genetically; but rather all are in controlled stages of investigation. Such a liberation of these organisms to the Environment, it is regulated legally by the Decree-law N° 190 about Biological Security, corresponding to the year 1999.

Cuba, as country signatory of the Protocol of Cartagena has more than enough Security of the Biotechnology, of the Agreement about the Biological Diversity, it instituted a Technical Committee of Normalization, dedicated exclusively to the matter of the foods obtained by biotechnical means, which centers its analysis, discussion and conclusions on the development and the legislation this topic.

It is the Institute of Nutrition and Hygiene of the Foods, adjunct to the Ministry of Public Health, the one in charge of to authorize and to guarantee the security of foods, so much cared as those object of national production, for their free sale and commercialization in the whole country; therefore, also load with the responsibility of assuring the non-dangerous and the sanitary registration of the transgenic foods.

It fits to mention that the juridical base on the topic goes for the Law N° 41 of the Public Health, corresponding to the year 1983, until Decree-laws and Ministerial Resolutions; all effective since 80's decade (31-34).

But, although the Laws and the mentioned Resolutions can be applied to the transgenic foods, the methodologies and sanitary regulations have not still settled down for the evaluation of the safety and the nutritional aspects, as much for the national products as of import that are sought to market in Cuba. Aspect this that should take in consideration for the Cuban legislator, keeping in mind that a bioethics focus and scientist will allow that the transgenic foods transform into a road more than he helps to increase the readiness of foods at world level.

Regarding the Intellectual Property in our country, as developing nation that is, it is necessary to say that such rights could constitute a barrier that impedes the access from the society to the biotechnical new inventions; but it is unmarked of the rest of the countries which share such a condition, like they are most of those of Latin America, in the sense that the politics of prevailing Intellectual Property, for reasons of state will, has as mission to impel the development of the biotechnical industry in benefit of the Cuban society.

Cuba is not UPOV signatory, although it is of the agreements TRIPS of WTO, and part of its rules stays reflected on our internal legislation. The Ordinance-law N° 68, about Inventions, Scientific Discoveries, Industrial Models, Trademarks and Geographical Indications, effective from 1983—which it was modified on its article 39, for the Ordinance-law 160 of 1995— only grants protection to the biotechnical products through Certificate of Author of Invention, which constitutes an equivalent title to the invention patent, but it differs of the same one in that said certificate guarantees the biotechnical product that fulfills the patentability requirements, demanded by the juridical classification, be in hands of the State; what guarantees a commercial exploitation directed to complete the social function that, so much ethical as legally, is demanded to the biotechnical science in Cuba.

In the Project of Code of Professional Ethics of the Workers of the Science in Cuba, corresponding to the year 1993, there are ideas about that "the activity of the worker of the science represents the singular characteristic that in her it is present, on one hand the necessity of the collective work and on the other hand, the function of the individuality manifested by its personal"(35).

In our country, the Programs Scientific-technicians constitute projection tools, guarantors of the investigations focused toward the social, economic and environmental main interests of the Cuban Government. It is the Government who finances and manages the projects of more possibility of success, according to their quality and their impact in the economic, scientific and social environments. As same it finances the patents, which

constitutes a highly expensive, but necessary process for the insert of Cuban products in the international market.

In contrast to the compulsion of respecting the regulations of TRIPS in the national norms of patents, the developing countries should achieve a system of protection, in agreement with the international contracted commitments that, at the same time, diminish the effects of this regulations as much as possible, taking advantage of the breaches that the system leaves open; as a way to opposing to the privatization of knowledge, facilitating the access from the society to the advances of the science and the technology. One of these breaches could be excluding of the patentability certain biotechnical products; as same also, to implant enforcement of exploitation of the product or patented process, to allow the disposition of the patented product by means of an obligatory license, in order to go against those abusive acts of the holders of patents rights.

10. CONCLUSIONS

After this review we can arrive to the following conclusions. The derived products of the genetic modification of the plants involve benefits and necessary risks of considering when deciding on the generalization of the same ones; for what the order words that it is imposed are the balance; as well as the setting in practice of political socio-economic not governed by the mercantilist vision of many of the holders of rights of Intellectual Property on this products, but for the will of the states of making that the benefits of the modern Biotechnology arrive to all. The conjunction of the principle of caution with that of sustainable development, when the plants modified genetically generalizing, they will guarantee the necessary balance; offering to the consumer of such products the possibility to opt for those modified genetically or to prefer those of organic character, without modifying. The Intellectual Property offers the possibility of a *sui generis* protection for the plants modified genetically, different from the protection for invention patent and of the rights of the owner of vegetable varieties. For what is to will of the States settling down political of more rigid or more flexible, more closed or opening, permissive Intellectual Property or not of the legal help of biotechnical products that you/they have genetic incorporate material of the plants or sequences of DNA; as well as to define in hands of who they are these rights of Intellectual Property. In Cuba, the Intellectual Property and the genetic modification of the plants, through the biotechnical new techniques, they travel of the hand toward the attainment of the end that the whole society benefits of the results of the application of such practices. As much the scientific politics as the artificial of Intellectual Property are traced by the Cuban State who subsidizes the science; focusing it, in that way, toward the increase of the quality of life of the Cuban society.

11. ACKNOWLEDGEMENTS

Negrin-Ruiz, A. & Pino-Rivero, L. thanks information support from Biotechnology of Plants Institute (BPI), as a manager center in plants genetic manipulated

experiments at Central University of Las Villas since 90's decade. All authors also acknowledge the Regulatory Frame of Climatic Change Project, still on execution, specially to Dr. Pascual Felipe Correa Álvarez, for his tutoring work and his experience as an investigation project leader.

12. REFERENCES

1. Benbrook, C.: Who Controls and Who Will Benefit from Plant Genomics? *The 2000 Genome Seminar: Genomic Revolution in the Fields: Facing the Needs of the New Millennium*, AAAS Annual Meeting (2000)
2. Warburg, R. J., A. Wellman, T. B. Buck & A. Ligler Schoenhard: Patentability and maximum protection of intellectual property in proteomics and genomics. *Pharmacogenomics*, 4, 81-90 (2003)
3. Segre, M. & E. S. Iwamura: Bioethics, intellectual property and genomics. *Rev Hosp Clin Fac Med Sao Paulo*, 56, 97-102 (2001)
4. Thomas, S. M.: Genomics and intellectual property rights. *Drug Discov Today*, 4, 134-138 (1999)
5. Abraham, D.: Managing genomics-based intellectual property. *Nat Biotechnol*, 16, 203-4 (1998)
6. Eisenberg, R. S.: Intellectual property issues in genomics. *Trends Biotechnol*, 14, 302-7 (1996)
7. González-Díaz, H., G. Agüero-Chapin, C. R. Munteanu, F. Prado-Prado, K.-C. Chou, A. Duardo-Sanchez, G. Patlewicz & A. López-Díaz: Alignment-free models in Plant Genomics: Theoretical, Experimental, and Legal issues. In: *Advances in Genetics Research*. Ed: M. A. Osborne. Nova Sciences, New York (2010)
8. Riechman, J.: Recombinnig arguments about cultivation and transgenic food. Ed: Los Libros de la Catarata, Madrid (1999)
9. Marshall, J. M.: The Cartagena Protocol and genetically modified mosquitoes. *Nat Biotechnol*, 28, 896-7 (2010)
10. Yamanouchi, K.: Regulatory considerations on transgenic livestock in Japan in relation to the Cartagena protocol. *Theriogenology*, 67, 185-7 (2007)
11. Kobayashi, T. & K. Yamanouchi: The Cartagena Protocol on Biosafety: implications for xenotransplantation. *Xenotransplantation*, 13, 10-1 (2006)
12. Sendashonga, C., R. Hill & A. Petrini: The Cartagena Protocol on Biosafety: interaction between the Convention on Biological Diversity and the World Organisation for Animal Health. *Rev Sci Tech*, 24, 19-30 (2005)
13. Pythoud, F.: The Cartagena protocol and GMOs. *Nat Biotechnol*, 22, 1347-8 (2004)

14. Freeman, L.: Leveling the field: answers to frequently asked questions about the Cartagena Biosafety Protocol. *Genewatch*, 16, 12-4 (2003)
15. De Greef, W.: The Cartagena Protocol and the future of agbiotech. *Nat Biotechnol*, 22, 811-2 (2004)
16. Gaugitsch, H.: Biosafety in the international context--the Cartagena protocol. *Environ Sci Pollut Res Int*, 9, 95-6 (2002)
17. Jank, B. & H. Gaugitsch: Decision making under the Cartagena Protocol on Biosafety. *Trends Biotechnol*, 19, 194-7 (2001)
18. Baran, M. & R. Yilmaz: The biosafety policy on genetically modified organisms in Turkey. *Environ Biosafety Res*, 7, 57-9 (2008)
19. Mousavi, A., M. A. Malboobi & N. S. Esmailzadeh: Development of agricultural biotechnology and biosafety regulations used to assess the safety of genetically modified crops in Iran. *JAOC Int*, 90, 1513-6 (2007)
20. Nasiruddin, K. M. & A. Nasim: Development of agribiotechnology and biosafety regulations used to assess safety of genetically modified crops in Bangladesh. *JAOC Int*, 90, 1508-12 (2007)
21. Hill, R. & C. Sendashonga: Conservation biology, genetically modified organisms, and the biosafety protocol. *Conserv Biol*, 20, 1620-5 (2006)
22. Tripathi, K. K.: Genetically modified organisms: concerns and biosafety issues. *Natl Med J India*, 15, 187-91 (2002)
23. Rodríguez-López, M. A., M. C. López Martínez & R. M. Blanca-Herrera: Biothechnologic Patentability to obtain new food products. *Ciencia y Tecnología Alimentaria*, 3, 50-51 (2000)
24. UNCTAD-ICTSD: Resource Book on TRIPS and Development. Cambridge University Press, New York (2005)
25. Bercovitz, A.: The invention patent and the utility model. In: Industrial Property Reading Selection. Ed: Félix Varela. Havana (2003)
26. UPOV: International Convention for the Protection of New Varieties of Plants. UPOV Convention, 1991 Act (1961)
27. Gonzalez-Diaz, H., F. Romaris, A. Duardo-Sanchez, L. G. Perez-Montoto, F. Prado-Prado, G. Patlewicz & F. M. Ubeira: Predicting drugs and proteins in parasite infections with topological indices of complex networks: theoretical backgrounds, applications, and legal issues. *Curr Pharm Des*, 16, 2737-64 (2010)
28. Gonzalez-Diaz, H., A. Duardo-Sanchez, F. M. Ubeira, F. Prado-Prado, L. G. Perez-Montoto, R. Concu, G. Podda & B. Shen: Review of MARCH-INSIDE & complex networks prediction of drugs: ADMET, anti-parasite activity, metabolizing enzymes and cardiotoxicity proteome biomarkers. *Curr Drug Metab*, 11, 379-406 (2010)
29. Duardo-Sanchez, A., G. Patlewicz & A. Lopez-Diaz: Current topics on software use in medicinal chemistry: intellectual property, taxes, and regulatory issues. *Curr Top Med Chem*, 8, 1666-75 (2008)
30. Ponce-Collado, A. & M. Álvarez-Gil: Transgenic Food in Cuba. Ed: Pharmacy and Food Institute, Havana University, Cuba (2006)
31. Resolution N° 215 about the Sanitary State Inspection. Ministry of Public Health (1987)
32. Resolution N° 64 for the Registration of Foods. Ministry of Public Health (1997)
33. Resolution N° 867 for the Evaluation of Pesticide. Ministry of the Agriculture (1989)
34. Decree-Law N° 54 about Sanitary Basic Dispositions (1982)
35. Project of Professional Ethic Code of the Science Workers in Cuba. Havana (1993)

Key Words: Biotechnology, Genetic Engineer, Plants genome, Organisms genetically modified, Vegetable variety, obtainer, Intellectual Property, Patents, Sui generic protection, Bio-security, Bioethics, Review

Send correspondence to: Anisley Negrin Ruiz, Department of Civil Law, Law Faculty, Central University of Las Villas (CULV), Santa Clara, 54830, Cuba, Tel: 5342281273, Fax: 5342281273, E-mail: negrin@uclv.edu.cu