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Legal, Commercial, Medical, Ethical and Environmental Aspects of Granting Patents for Biotechnological Innovations

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Abstract

Biotechnology has many applications in environment (clean up or prevent its degradation), agriculture (increased efficiency and productivity), medical (new methods of treatment or new drugs) and various industries, including Oil industry (elimination of oil pollution), textile products (increasing the quality of textiles) and food industry (raising the quantity and quality of food). But there are also concerns relating to some unknown aspects, effects and consequence of biotechnology in a way that the long-term effects are not so clear on human health or on the environment in the agriculture and in the food industry on the health of consumers. For example, gene therapy and genetic drugs, can cause some genetic complications or biotechnological product may cause growth of useless or harmful like weeds resistant to pesticides and even pollute the environment by disrupting the function in agriculture. Of course to address this concern, there are some principles such as biological safety and the necessity assess the risks arising from the use of this product, and prudent use of these innovations on the domestic and international level. Ethical considerations and objections have been raised by the moralists in terms of loss of intrinsic value of life due to manipulate by biotechnology or threaten the dignity of living creatures with dominance and monopoly over them. These considerations will be strongly when we are confronted with the fact that the granting of monopoly to biotechnology can lead to the misuse of this knowledge against humans and other organisms. Of course, there are ways to prevent or address these abuses, including the abolition of the patent or parallel import of product or granting licenses to others. In addition, human rights lovers also believe that the granting of monopoly and patent to the achievements of this science is In some cases contrary to human rights So have objected to it. Like threaten the right to health and healthy food (in terms of risk to human health resulting from biotechnology. Threaten the right to work (due to market monopolization by big companies and unemployment and the gradual elimination of small farmers) and threaten the right to a healthy environment (due to possible adverse effects on the environment and biodiversity). Of course, these concerns can be reduced by international regulations such as the Cartagena Protocol on Biosafety. Another challenge is on how to prove damages resulting from biotech crops to the environment, people and their property and also proving the causal relationship between the biotech and damage is difficult because their harmful and unknown effects usually becomes apparent in long-term and this makes it hard to prove a causality relationship. Also in such damages, the best way of compensation (i.e. restore the former state) is difficult or impossible. Because the reproducibility of biotechnology can reduce the ability to control on extent of damage and the harmful effects. However, concerns have been reduced slightly by stipulating strict liability for the damage in international regulations.

Keywords: biotechnology, patent, protection system, practice of governments, international challenges

1. The Challenges of Legal Regulations Related to Biosafety of Biotech Crops

1.1 Concept, Necessity and Components of Biosafety

As has been shown throughout history always with the development of new science and technology, problems have also emerged. Since the beginning of the application of biotechnology, many scientists expressed concern about the safety of using this technology. And the risk in handling a piece of genetic material of an organism to other organisms. Thus, applying a precautionary approach in all areas of application of this science leads to new insights on the birth of modern biotechnology as a biological safety. Biosafety includes application of a series of measures, standards, policies and procedures that reduce or eliminate risks of working with dangerous biological agents. If done violation of biosafety, naturally there is the possibility of loss. For example, any biological nature that has the ability to reproduce or transfer of their genetic material, could be hazardous. Any organisms have a new combination of genetic material is potentially dangerous and risks related losses may occur .In relation to other living organisms related to agricultural production, including agriculture, horticulture, forest, grassland, deserts, fisheries, livestock, poultry, beekeeping and poultry food, pests, diseases and biotic factors associated with these cases (Najjar, 2005, p. 6).

The first non-enclosed release of modified organisms in the natural and agricultural environment, in order to reproduce or commercial production, may have its own risks. In food and cosmetics as well as additives and dyes used in them will have their own specific effects of these hazards. In exports and imports may also demonstrate their losses. Intentional transboundary transfer of the modified organism to outside the official borders of the country or vice versa, is not safe.

All of these risks and potential losses are likely and it is possible despite the above measures that losses are not entered. And of course, regardless of the responsibilities related to prevention, as long as not to harm, there is no compensation. However, it should not be ignored the responsibility to prevent and avoid possible losses and related obligations in the Convention on Biological Diversity and its Protocol (Darabpour, 2010, p. 51).

Some components of biosafety are pre-release Such as parents search for plants, transgenic and the process of releasing it. As well as some biological safety components are also related to post-release. For example, assessing risk of environmental hazards, including the Identify all possible risks and claims, Characterization and their properties, Determine the probability of each of the alleged risks, and evaluating the effects and consequences of risk (Tohidfar, 2010, p. 4). Such as the transfer of DNA from species to another, regardless of the natural parent to child transmission, which is called horizontal gene transfer (Khavari and Masomiasl, 2009, p. 28).

There are also theories about the possibility of sensitizing protein produced by genetically modified organisms in susceptible individuals (Uzogara, 2000, p. 179). Genetically modified foods contain known allergens (such as proteins, peanuts, wheat, eggs, milk, grains, nuts, fish, shellfish and crabs) can cause allergic reactions in susceptible individuals (Celec, 2005, p. 531). Engineering plants to produce toxic substances such as drugs and pesticides, can carry risks to non-target organisms. Due to the risks that are necessary to evaluate potential risks of genetically modified organisms. Theory of risk assessment of genetically modified organisms was discussed for the first time in 1975 at the Asilomar Conference (Fredrickson, 1979, p. 151) And then biosafety guidelines and conventions was designed that we explain them.

1.2 Regulation of International Biosafety

1.2.1 Biosafety Regulations in the Convention on Biological Diversity

The Convention has been accepted the potential benefits resulting from the use of transgenic biotechnology, along with the acceptance of the need to review and assess its risks and manage these potential threats. Article 8 of the Convention is considered to control the risks of GM crops. According to paragraph 7 of this Article, each of the member countries as possible and in an appropriate way, to create the necessary tools to set up, manage or control the risks inherent in the use of living modified organisms resulting from biotechnology… due to threatening complications for human health, or perpetuate to use it. The obligations set forth in Article 8 will be completed in the fourth paragraph of Article 19 by what it says: Each member of the country directly or by requiring any natural or legal person under its jurisdiction that provides transgenic organisms, should provide any information about the use of organisms and safety regulations required for their application by Member States. (Abbasi and Razmkhah, 2014, p. 16).

1.2.2 The Provisions of the Protocol on Biosafety

This protocol is the first legally binding international agreement on the trade of genetically modified organisms. According to the second paragraph of Article 2 Members shall ensure that the development, handling, transport,

use and release of genetically modified organisms would be in such a way that, taking into account the risks to human health, or prevent it from occurring hazard decreases.

The protocol, therefore in order to be more successful in achieving the objectives outlined in Article 1 is adopted precautionary approach. Among the noteworthy points in the system of the present protocol is "agreement has already been notified". In accordance with Article 7 all natural and legal persons who intend to import, export or domestic and cross-border transport of genetically modified organisms under this Act, have a duty to provide information and documentation required scientific assessment of risks based on the relevant provisions of the Cartagena Protocol on Biosafety to the executive agencies and receive the necessary authorization.

According to this system, the country has the right be aware of this transfer before the first import of biotech products, and have the chance to decide on the issuance of import permit and this decision should be based on risk assessment.
In this context, Article 15 is also significant:

Undertake risk assessments pursuant to the protocol on the basis of scientific correct way and taking into consideration known methods of risk assessment will be done. Such an evaluation should be available in order to identify and evaluate potential adverse effects of genetically modified organisms on human health (Arnold, 1993).

2. The Ethical Issues of Biotechnology Patents

Each technology is always a dark side and this is why, genetic engineering can also lead to unwanted results that is dangerous, inhuman and immoral genetic engineering has raised certain ethical concerns not only in the field of genetic manipulation of plants and animals, but more importantly, in the field of genetic interventions in the human genome (Bryant and Bagehot, 2009, p. 99). Advances in science and technology is faster than moral rules and supervision in that area. In case the benefits of genetic engineering will be greater than its risks that there is adequate supervision on that and to be considered ethical concerns related to it. According to the youthfulness of the technology and great opportunities that this technology can improve the situation of human life as well, can accurately assess ethical aspects of genetic engineering to insure the future of it (Rahnama and Sanjarian, 2011, p. 2).

Apart from scientific concerns about biotechnology are also a series of objections and mere ethical concerns. Objections of moralists about biotechnology are raised on the grounds that the life because of the inherent dignity and in their natural form (not modified by humans) is a valuable. Of course, there are some views on dignity that do not consider changes in genes even human genes, whether to fix defects and problems or to improve function, as an inherently wrong action. In fact, the inherent dignity requires that we have to keep track of time in the area of genetic engineering research that can help to improve and develop therapies to those who have limitations have been naturally or as a result of the accident (Bostrom, 2003, p. 493).

It is obvious that human dignity requires that we restrict the genetic engineering. Every human invention that is used to humiliate important capabilities such as cognitive function, would be unethical. Thus, while the use of some human races who are genetically engineered as slaves, it clearly would be a clear violation of human dignity (Cooley, 2007, p. 209). Moreover, another problem related to justice and equality is also about biotechnology. For example, genetic interventions, especially genetic improvement (by contrast, genetic incapacitation) may increase existing inequities.

As with any new and expensive medical technology, medical procedures that use uncommon genetic interventions likely lead to classify customers and services.There will always be some people who have access to this new technology while others will be deprived of these facilities. Inequality in access to technology provides a clear concern for social justice, especially when treatment or services are medically necessary, but due to high cost, there is no possibility of achieving it for everyone. (Rifkin, 1991, p. 388).

3. Human Rights Concerns Related to Biotechnology

Biotechnology with its key achievements and various applications in the fields of industry, agriculture, environment, medicine, animal husbandry, food, has made more progress and prosperity of human life. But all these things not caused that international human rights law not react to some worrying about the human rights aspects of biotechnology. For example, biotechnology can have devastating effects on the environment and biodiversity and threaten the right to a healthy environment or eliminate the right of small farmers to work by creating commercial monopolies for biotechnology companies or threaten the right to health and healthy food of consumers so here it is necessary to examine the content of these concerns.

3.1 Biotechnology and Right for the Environment

Environmental problems caused environmental regulation to become essential in the international arena (Ziaran, 1994, p. 472). The right to a healthy environment was gradually recognized and was identified as one of the rights of third-generation human rights (Solidarity rights). There are two aspects of individual and collective right to a healthy environment. In individual aspect, any citizen has no right to harm and damage the environment in any way (here through biotechnology risks). In this regard, damaged persons the right to present a claim in case of damage to the environment. The collective aspect of this right relates to the duty of the government. Where governments are obliged to work together in solving global environmental problems (Abbasi, 2011, p. 452). Among the international treaties, several documents have adopted in the right to a healthy environment. The most important of these documents are: the Stockholm Declaration, the World Charter for Nature, the Rio Declaration. Some human rights documents that have been adopted by the United Nations considered the right to a healthy environment as a fundamental human right (Molaei, 2007, p. 278). Considering that biotechnology can have bad effects Such as loss of biodiversity and genetic contamination and horizontal gene transfer and increased resistance in target organisms and increased use of chemical herbicides, so faced with these challenges that can affect their rights to a healthy environment. Of course the obligation to assess the risk arising from the use of biotech crops can reduce some of these concerns.

3.2 Biotechnology and the Right to Health (Healthy Food)

In the framework of international human rights law, the right to food is a fundamental right that provides every person has right on sustainable access to food that meets nutritional needs and has no toxic and hazardous elements. GM food and feed products due to their complications for consumers, causes serious concerns among human rights activists.

Today only feed the people and freedom from hunger, is not considered, but also in ensuring the right to food, food products should be considered to be healthy and safe. It is an issue that has been raised as a human rights challenges facing the new technologies of production and supply of food products, including biotechnology. Corn, soybean, canola and cotton resistant transgenic seeds are some of the most important pests, which have the largest area under cultivation in 2013 in the world (Clive, 2014, p. 12). But their use is associated with unpleasant side effects among consumers (Bagheri, 2007, p. 15).

Governments have a series of national and international commitments in terms of providing the right to safe food and must monitor their food system. The monitoring starts from farms and food production and expands to markets selling food and Food safety testing. Government responsibility placed it in a wide range from determination of the minimum wage and land ownership laws to control food quality and direct participation in food production (Narula, 2006, p. 725). With all the advances in genetic engineering, there are many issues still unresolved. For example, one of the serious concerns about transgenic plants is that some of these products are allergy-causing gene. This sensitivity is caused by the consumption of transgenic plants and their products. Genetically modified foods may contain toxic materials (Pradesh, 2006, p. 6).

3.3 Biotechnology and the Right to Work

The right to work within the framework of international humanitarian law is the fundamental right of everyone to sustainable access to decent work that meet the needs of the livelihood and well-being. Both of urban communities and members of rural communities have it. Supply GM seeds, the grant of exclusive rights to private companies producing seeds, selling seeds to farmers at exorbitant prices, Unable to save seeds and other factors, led to impose widespread financial restrictions on the body of poor farmers and vulnerable communities. This resulted in the removal of small farms and poor farmers of the stock market and their entry into the false jobs market (Kruft, 2010, p. 2). Intellectual property rights enforcement in relation to plant genetic material, limits farmers to use seed (Robinson, 2011, p. 45). Several studies show that GM farming leads to a shrinking labor force needed for cultivation the same amount of product and, consequently, will result in unemployment of the number of farmers (Rulli, 2007, p. 20).

4. Medical Risks Related to Biotechnology

4.1 Concerns about Protection of Pharmaceutical Biotechnological Inventions

The first challenge of pharmaceutical inventions from the perspective of developing countries is to grant exclusive rights to the inventor of the increase in drug prices and access it more difficult for patients because the following costs should be added to the cost of production Such as the costs associated with obtaining regulatory approvals, including approval of the efficacy and safety of medicines And the cost of patents and marketing and commercial costs for drugs.

Supporters of perspective of conflict between intellectual property rights and human rights, have announced one of their documentation that intellectual property rights conflict with the principles of human rights, for example, the right to health. This means that countries, whether in the national or international level should not restrict access to medicines by legal or economic measures. The government to fulfill this commitment requires a comprehensive plan for the realization of the right to health. Granting an exclusive right to the inventor and drug and pharmaceutical companies, resulting in increasing drug prices could make a dent in fulfilling the above provisions and constitutes a breach of the principle of access to health. Also, granting of the patent is contrary to the principle of prohibition of abuse of rights. The purpose of this principle is that one cannot and should not harm others by exercising their right. This principle is one of the best examples of the general principles of international law (Movahed, 2002, p. 371).

Opponents believe that the protection of pharmaceutical inventions and granting patents to inventions dealing with life and human health can provide grounds of abuse by Patent owners of their monopoly position because the production and proliferation of drugs is in his hands and if he opposed to production, ability to save a lot of patients goes away. And if he does grant the license subject to payment of a large fee, drug price rises and re-created an inhuman result (Salazar, 1999, p. 71).

4.2 Legal Solutions Integrating Health and Intellectual Property System of Biotechnological Inventions

Compulsory licensing is one of the solutions that exist in most intellectual property laws in cases of abuse of rights such as not using the right holder of their rights without just cause and not to grant licenses to third parties with fair conditions. Exploitation of compulsory licensing by the government is to use the invention by giving the holder the exclusive right to fair remuneration that will be given patents in favor of a public institution or a third party and private institutions. Article 6 of the TRIPS agreement to developing countries and small economies has been very attentive and allowing parallel imports to authorize the countries according to their laws, for developing countries and the least developed, parallel imports, in case of high drug prices is as a very important solution for access to medicines and the health and social care as well. Moreover, when the domestic production of the drug is not possible and the problem cannot be solved with the use of compulsory licenses, parallel imports can be considered as a means of securing access to medicines (Rahnama, 2008).

5. Adverse Effects Related to Environmental Law Due to Protection of Biotechnology Inventions

5.1 The Role of the Patent System in Increasing Adverse Environmental Effects of Inventions

Along with the becoming more common, theory of utilitarianism considered as a philosophy to justify legal protection of inventions and scope of patent protection of inventions has increased along with the emergence of new technologies. Too much focus on the protection of industrial progress gradually causes inattention and neglect of the side effects of this approach was as the laws of patent protection the various types of invention regardless of their adverse environmental effects, but there is a question that is modified plant and animal products despite the benefits, harmful to the environment and specifically to biodiversity? The truth is that in the case of a new species of plant or animal, is done multiple and long-term tests at different stages. But despite these proven that sometimes the transfer of alien species to a new area can alter the biodiversity area or has produced weeds or acted such as an invasive species and alter ecosystems and their biodiversity. Accordingly, the convention on biological diversity provides that member states shall, to the extent possible, prevent the introduction of invasive species threatening native species or ecosystem or control them. However, the country has not taken effective measures in this regard, and there are no effective national and international laws (Rozec and Berkowise, 1998).

Of course, many of the issues that cause concerns about biotech crops such as herbicides and pesticides are harming non-target organisms, escape transmitted characters and the creation of weeds and like them, are common concerns in traditional agriculture (Pool and Joan, 2001, p.8). Of course, this fact should not cause a lack of caution about the effects of biotech biotechnology, but on the other hand should not cause fear.

5.2 How to Reform the Patent System to Protect the Environment

One of the foundations of the theory of utilitarianism is improving the material conditions and welfare of human beings. In the meantime, it should be noted that a healthy environment is also part of the same condition. Because of the need to protect the environment and natural resources, should be reviewed in the theory of utilitarianism utilize the patent system as a tool to protect the environment. Patent law reform based on the new concept of the doctrine of utilitarianism would mean that inventions have a negative impact on natural resources should be protected by law. Also can be applied more flexibly, the terms of those innovations that help to maintain and enhance the environment in a way that facilitates the groundwork for the development of such

innovations. According to the judicial practice of various countries including Europe, Protection of the environment, natural resources and life of humans and other animals is one of the main elements in the field of public order. Hence it can be concluded that the inventions that reduces biodiversity and damages to the environment, they are not compatible with public order, therefore, must be regarded as inventions excluded from registration (Bonfanti, 2012, p. 48).

6. Misuse of Exclusive Rights of Biotechnological Patents

The intellectual rights holder has exclusive rights and the legislator has granted them the right to exploit these rights. It also has provided remedies to protect and secure the exclusive rights. Granted right is not absolute and may also be abused and restrictions on the exercise of this right should be considered. So the doctrine of abuse of the right is for avoiding aggression the intellectual property rights holders in the legal system. The doctrine of abuse of intellectual property, means the misuse of exclusive rights granted to the holder of the rights that would be prejudicing third parties and the public interest. Misuse of the right is completely unacceptable and must be controlled and monitored to prevent harm the interests of others because grant an absolutely right cause people to operate their right to the detriment of others (Bahrami Ahmadi, 1991, p. 104).

6.1 Common Examples of Misuse of Patents

Right holders refuse to grant licenses on commercially reasonable terms to the applicant and the non-use of patents or the inadequacy of exploitation... are examples of abuse of rights. As well as improper disclosure of the invention, the inclusion of clauses in the contract unilateral transfers and create a barrier to free trade, unusual increase in the price of pharmaceutical inventions, conditional transfer agreement to accept the obligations unrelated to the subject of the contract, preventing parallel imports, no exploitation or inadequate exploitation, inadequate production and supply are also other examples.

6.2 Strategies to Deal with Abuse of Patent

If the right holder has no legitimate reason to avoid granting licenses and reject the proposed transaction, he violates the rules of competition law and also abused of its exclusive right. In which case the cancellation of the patent is a solution. On the other hand, if the right holder is not committed abuse and products in sufficient quantities to supply the applicants, but collective interest requires that protected product, without permission of the right holder and in return for a fair consideration, is in the hands of people. This approach is called a compulsory license. In fact, a compulsory license to exploit, a tool that establishes the necessary balance between private rights and public rights. National defense, national economy, public health and the things that are in the interests of the public.

7. The Challenge of Proof of Liability and Compensation Resulting from Biotechnology

A number of challenges relate to the risks and damage caused by biotechnology. Here must pay for the damages through biotechnology and then analyze how to compensate for these losses.

7.1 How to Enter Environmental Damages Arising from Biotech Crops

Undoubtedly, we can say that there is a possibility of damage due to the potential biotech operations. These risks emerge in various areas including the environment, humans and animals (Rifkin, 1991). Whenever a genetic stock is released on the nature, there is always the possibility that disrupt the order of the environment. Because these creatures as non-native species, enter artificially to complex and intertwined environment that a series of highly integrated relationships in the evolving history is formed, Entry of any abnormal species can lead to the disruption of the established order (Rifkin, 2003, p. 145).

Destruction of eruption feature of the soil, Loss or destruction of a variety of nutritious plants, increased carcinogens in water and soil organisms that reduce lifetime and fertility, are among other risks arising from the use of this technology (Khansar, 1998, p. 74). The use of genetic engineering in animals causes adverse effects both for animals and for human.

7.2 Proof of Elements and Foundations of Responsibility for Damages Resulting from Biotechnology

Traditional civil liability based on fault is not efficient in response to environmental damages. One of the reasons for the failure of civil responsibility in this regard is that victims have little incentive to pursue environmental damages and claim environmental damage. It is very difficult to prove causality in environmental damages and assess the environmental damage and in some cases it is out of power of courts and in many cases, because the environment is not private property, therefore there is not the condition of civil responsibility for individual property rights violations. For example, one does not demand compensation for damages from the spread toxins that can cause lung and respiratory sensitivities (Shafer and Ott, 2004, p. 241). Thus proving this relationship

will be successful in very few cases.

Another problem related to the environment is that many damages to persons and the environment by polluting activities, especially physical damage show itself too late and this can create ambiguity and complexity in the proof of a causal relationship. Many countries have found that the traditional rules are not enough to meet the legal problems caused by the production of this product. Among the reasons that can be mention to determine the need for a special responsibility regime for the biotech products, is the risks and damage as a result of the production and distribution of these products, including human losses and environmental damages and this feature is rarely seen in the other goods or products (Jafaritabar, 1996, p. 42). Moreover, problems of general principles of responsibility, including the need for consumer protection, the difficulty of proving the guilt of the person, uncertainty of all hazards and defects biotech crops as well as the difficulty of determining the harmful agent, can be that example that requires to determine a specific regime's responsibility for these products.

So liability arising from biotechnology products was considered in the additional Protocol Nagoya-Kuala Lumpur. One of the purposes of this protocol is providing international rules and procedures on liability and compensation for damage caused by genetically modified organisms. Article 4 is one of the most important provisions of this protocol. According to which a causal relationship should be exists between losses and genetically modified organisms. So create and proof of a causal relationship to the person responsibility is enough and this is very close to strict liability.

In all responsibility issues dealt with in this protocol, did not speak of failure or negligence or fault of the responsible person and only the proof of a causal relationship is emphasized. This protocol refers to one kind of responsibility that unlike absolute responsibility is limited and if the damage caused by natural disasters or force majeure, responsible person (the agent or operator) is exempt from liability (Badini, 2005, p. 218).

7.3 problems Related to the Compensation Methods for Damages Resulting from Biotechnology

Compensation arises if the elements and conditions of civil liability exist. Compensation depending on the type of damage can be done in different forms and methods and Due to environmental and biodiversity impacts on the human environment and natural resources, can be paid to compensate each of them. Obviously, the ideal method of compensation is restoration of the injured person to the situation prior to the damage occurrence. In this way, the injured party would be restoring the situation before damages as if not to harm from scratch (Katozian, 1990, p. 324). In some cases it is impossible to do this and financial compensation is the only practical way of compensation. Of course, this approach will not compensate for losses that have arisen since the damaging action to return to the former status (Haji Azizi, 2001, p. 64). So this method is applicable to compensation if it is feasible. Thus, solutions have been proposed if the compensation is technically feasible and possible. Including replacing dilapidated natural resources and infest with equivalent resources and if the cost of replacing is disproportionate, a financial compensation is done and the amount of damages in accordance with the value of natural resources.

8. Conclusion

According to the functions of biotechnology in different fields, various industries from medicine to agriculture and animal husbandry, it is essential that as in other areas of technology, a legal protection of biotechnological inventions comes into existence. Since it is the invention of the human mind. One of these legal protections is granting a patent to its invention. However, due to some unknown aspects and results of biotechnology, take any decisions concerning the extension of patent law to biotechnology innovation must be done carefully and consider all aspects of the issue.

Although biotechnology and its applications have protections in the international and domestic legal, But there are also challenges concerning the protection of biotechnological inventions, including challenges related to the legal provisions of the biosafety biotech crops because the displacement of pieces of genes an organism to organism is risky and led to new insights on the birth of modern biotechnology as biosafety.

There are also ethical concerns about patents and moralists objections based on conflict of biotechnological manipulations with the intrinsic value of life and the dignity of living beings. Lovers of human rights have human rights concerns since biotechnology can have bad effects like the loss of biodiversity and genetic pollution and increased resistance in target organisms and increased use of chemical herbicides so can affect the right to a healthy environment. The GM food crops and complications caused by fed up with it (sensitivity and toxicity) can also affect the right to healthy food. As well as granting exclusive rights to private companies producing genetically modified seeds, it has imposed extensive restrictions on the farming community and it has caused a reduction in the number of small farms and remove weak farmers and threatening their right to work.

Medical risks related to biotechnology are other concerns and challenges. Therefore, the granting of exclusive rights to the inventor of the increase in drug prices and makes it harder for patients to access it and threatens access to health.

The role of the patent system in increasing adverse effects of environmental innovations, is another challenge. As a result of focusing too much on the support of industry developments and neglecting their adverse environmental side effects. So that genetic manipulation of organisms of different species of flora and fauna changes in natural diversity of native varieties. Another challenge in granting support to biotechnology patents is the risk of misuse of the exclusive rights of the patent. Right holders refuse to grant licenses and the non-use of patents or the inadequacy of exploitation and improper disclosure of the invention, an increase in the price of vital inventions, preventing parallel imports, no exploitation or inadequate exploitation, inadequate production and supply. The way to deal with it, is the cancellation of patent and allowing parallel imports. Another challenge of the use of biotech crops is establishment of responsibilities and how to redress the effects of biotechnology. In biotechnology naturally there is the possibility of prejudicing for example, reproduce or transfer of genetic material can be dangerous. And in case of damage caused by these risks, agent of losses should be responsible. There are many elements necessary for the realization of this responsibility that lack of any of them will be prevented from liability. In liability, it is essential that there are three pillars: loss, harmful act and the causal relationship between them. Of course, there are challenges in damages of biotechnology and in proving any one of these three elements.

For example, demand should prove that biotechnology is the cause of loss and it is very difficult to prove and the need for scientific and technical knowledge and any person cannot have such expertise. Also a lot of damage to people and the environment appear too late, especially physical damage caused by pollutants such as biotechnology activities, and this could lead to ambiguity and complexity in the discussion of causal relationship. As a result of these problems, experts and protectors of the environment in these cases, have reversed the burden of proof the claim to make it easier to prove causality. International efforts to address this challenge led to ratify the Nagoya-Kuala Lumpur additional protocol. According to which there must be a causal relationship between the harm and genetically modified organisms and establish a causal relationship is adequate and this is very close to strict liability. If, for example, the damage caused by natural disasters is unpredictable or person in charge is exempt from liability. In the end, it should be noted that there are problems in the procedures and methods to cover losses on biotechnology. The preferred method of environmental damage resulting from biotechnology, is the restoration of the situation of the injured to the outbreak of damage but that is not possible in all cases. As well as alternatives (i.e. compensation with money) are also faced with this problem that environmental damage can hardly be measured with money.

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