Intellectual property in biotechnology: protection of the natural genomic resources and ownership of the genomic data

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1. Introduction

Intellectual property rights are protected in the following ways: by patents, trade secrets, protection of plant and animal varieties (applied mostly in "classical" agriculture), copyright, and copy protection rights used usually by writers, artists and authors (e.g. computer programs), trade marks, registered designs.

Patents, trade secrets and plant and animal protection rights are commonly used in the case of biotechnology achievements. (Several articles concerning these problems have been published, mostly in Polish, in the journal "Biotechnologia" (1 – 11 and papers in this issue). We observe many high level initiatives concerning future development of the legal status of biotechnology, in which several governments and the United Nations are engaged (cf. 4,8,9,12 – 17). However, there are several serious problems, unsolved in most countries, concerning specific issues, which we might call "peripherals" of biotechnology. The term "peripherals" is true as long as we do not take into account the significance and economic background of the subject. The following problems — among many others — are worth being highlighted:

* Rights of the access to information concerning future experimental projects and their expected prospective effect(s) on the environment.

* Rights to protect confidentiality of results, particularly of the preliminary ones with high level of uncertainty concerning humankind.

* Rights to unlink the data from the names of persons; protection of confidentiality of the suspects and results.

* Ownership rights to the analytical and particularly to the genomic data concerning people.

* Scientists' and industrialists' rights to perform an experiment and to take reasonable and substantial risk as well as freedom to refuse doing a research, experiment or being an object of an experiment.

* Protection of local genomic resources (particularly in the 3rd world).

Public opinion plays a significant role in the determination of limitations for science and technology. This is the obligation of the scientific society to

explain and to popularize the real, scientific picture of biotechnology. The main goal should be to evaluate the reasonable and acceptable for the society risk associated with the progress of science.

I would like to focus on two specific aspects:

1) protection of natural genomic resources, and

2) ownership of the genomic data.

Many "worries" concerning genetic engineering have significantly inhibited the research progress. Today, in my opinion, we should stress the positive and fruitable aspects of modern biotechnology to accelerate its further progress. Presenting the two indicated topics I am going to show questions and suggestions of constructive answers how to improve the present picture of the situation.

2. Importance

Both problems are very important, though much less attention has been paid to them than to others. The "standard" ways of protection of intellectual property rights are not sufficient in these two indicated cases. I would like to illustrate the problems by the following examples:

The United States of America did not sign the agreement concerning the protection of biological diversity (so called "Biodiversity Convention") during the United Nations Conference "Earth Summit" in Rio de Janeiro (3 – 14 June, 1992)*.

In common opinion, this Convention will prevent giant pharmaceutical companies from using genes isolated from biological material originated in the third world countries. On the other hand, the companies claim that this Convention will limit their patents and intellectual property rights to the products and processes which include genes from rare, exotic species. However, and this has to be stressed, most of the countries are not able to take advantage of their own genomic resources. Technical limitations, lack of know-how and of highly qualified personnel limit the application of modern technology in many places around the world where rare cultivars exist. The intention of the Convention was not only preservation of genes but also transfer of technology from the well developed and technically advanced countries to the 3rd world.

Article 15 of the Convention defines the national property rights of the state to all microorganisms living in a countries' territory. This should lead to the recognition of the national regulations. Following the ideology of the Convention the rich Western states should transfer the genetic engineering technology and know-how preservation of genetic resources to poor countries.

* For general comments concerning Earth Summit in Rio de Janeiro see cf. "Newsweek", June 14, 1993.

The production of a bio-pesticide: pyrethum is an example of the significance and potential profit from specific plant species. Harmful effects of chemical pesticides resulted in the boom of natural products. The compound called "pyrethum" is isolated from the flowers of pyrethum (*Chrysanthenum cinerariaeflium)*, grown in East Africa, mostly in Kenya. A USA company Agri-Dyne will develop and produce a genetically engineered *pyrethum* to enable US to become self-sufficient in this respect. Evidently, the American market, worth US $ 100 million a year, very soon will be closed for the African product.

Traditional crop improvement is a time and man power consuming process. Usually it takes more than 15 years to obtain a new cultivar. 5 further years are required to obtain commercialization and profit. Using the new genetic engineering technologies, an unfair competitor is able to find and isolate gene(s) responsible for the desired property(ies) in a new, valuable, commercially available, cultivar. Introduction of the particular single gene into wanted species is possible in a period of time shorter than one year. This "piracy" will be extremely difficult to follow and expensive to prove. Additionally, under the existing breeder's rights, there is no adequate protection against such violence. The same seems true in the case of "pirating" the natural genomic resources. At the present stage of knowledge and international initiatives we can formulate the following basic questions:

— how the 3rd world countries could collect profit originating from their natural genomic resources,

— how to support and how to protect against damage natural (like existing in Peru) and man-made collections of germplasm (e.g. Vavilov's centers),

— how to define and prove the property of a gene occuring in nature or in a germplasm collection.

Special attention should be paid to the promotion of conservation and efforts have to be taken to link users of plant genetic resources, farmers, breeders and genetic engineers, with people engaged in genomic resources conservation.

In the latter case, the following open questions can be posed as the example: how far will it go, who will own and use the results of Human Genome Diversity Project (HGDP)? The estimated value of the project is US $ 35 million; the funding available today for research about US $ 15 mln. This project is a subject of many discussions not only among the scientific society (cf. 18). The researchers want to collect and analyze the genes of 500 world's most stationary and isolated populations. There are some exotic populations with a small number of people. As an example we may present the research going on in Italy, on a tiny Tuscan village, with the population of 1815 inhabitants. It is expected that the villagers are direct descendants of the Etruscans, the pre-Roman people who settled in this area in the sixth century B.C. The DNA isolated from the blood of today's people will be compared with the DNA isolated from the bones of a more than 2000 year old original

Etruscan mummy. In this way, the continuity between Etruscans and today's Italians will be proven. The scientists responsible for the project believe that the genes will tell the whole story of the human family tree. This HGDP is strictly connected with the well known Human Genome Project (HGP). The genetic picture of mankind will be more clear when ethnic diversities will be taken into account. There are several "worries" related to this subject. The background of the questioning does not concern the technical aspects of the project but the ways in which the results will be used. An Afrikaner, a donor of blood for this project, may wonder what kind of magic has been done to his/her blood. In the past (and even today) we observed a lot of "very bad magic" concerning interpretation of the membership of a given ethnic minority. The basic problem is who will have the property rights to these data and what he/she will do about them? Any kind of public statement can be both positive and negative if the determination of membership of any "DNA-family" is followed by classification of people. Will scientists or anybody else use this attitude to form a human family tree with a commentary who is better? Such classification will result in a lot of emotion and very little of solid science. Before starting projects of this kind the following questions should be answered:

* **why** we want to know the genes and for **what**,
* **when** we want to know them,
* **what** sort of genes we are interested in,
* and last but not least: **why** we do **not** want to know the genetic information.

We have to remember, that basicaly the researchers are responsible for providing solid data. However, the scientific community has to think **how** the results of their research will be used.

The researchers (particularly medical doctors) are obliged to protect the confidentiality of medical subjects. Medical treatment and analytical data are protected by law. However, the scientific data (including medical analysis and results of treatment) are publishable. Such information in general should be unlinked from the personal data, before making them publicly available. The time and money necessary to obtain these valuable data should be compensated as soon as possible in the personal profit of the suspect of the research. These data can be used for further medical treatment or for family protection. In such a case, a personal file has to be available. But the data are charged with the uncertainty factor due to the technology available today. Evidently, some general rules have to apply:

— the data are strictly confidential,
— the data are owned by the tested people,
— the data are not available for insurance or employment purposes.

3. Present state in the Polish perspective

The aim of patent protection (1,10,11,19,20) is to secure the rights of an inventor. In the case of modern biotechnology, particularly genetic engineering, the key issue is to have a gene responsible for a desired function in the biological system. The genomic resources of nature are not protected like private property is. All of us are allowed to use them. However, this is a difficult task (expensive and requiring trained and talented teams of people) to find, isolate and make technologically useful a single desired gene. The properties of exotic animals and plants are of particular interest. Researchers hope to find and specify e.g. the protein(s) responsible for enifreeze properties of arctic fishes.

In Poland, on 16 October, 1991 (21,22) new legal regulations concerning protection of nature determined also the protection of national genomic resources. Paragraph 21.1. states the following: "(...)protection of biodiveristy of species and genetic resources(...)". The local state authorities are responsible for nature protection. All the national parks are treated as "gene banks" — sources of "genomic resources" and "biodiversity". Reproduction of rare and valuable natural species is protected by law and supported by the state. The disadvantage of the new law is the transfer of responsibility to the local administration; the qualifications of regional and municipial authorities are in most cases not satisfactory, at least in the case of protection of genomic resources. This form of protection of national resources has been chosen by several countries. The legislation and policies of protection of the natural environment have been enacted as early as in the '50s by such a remote country as Sarawak, East Malaysia.

The new Polish patent law (following the regulations of October 30, 1992) (23) satisfactorily modifies our regulations and makes them similar to those of the countries of United Europe and the USA. Total unification of legal regulations is practically impossible. At the moment, there are too many discrepancies between the European states and the rest of the world. Following the new regulations, it is possible to protect drugs, chemical compounds and food with patents. The following are patentable in Poland, similar as in other countries: techniques of isolation and identification (including gene technology), modified genes, technology of gene transfer and organism modification, new biological systems (cf. microorganism). However, the new legislation does not clarify some important problems e.g. the patenting of human genome (totally or in fragments).The question of great importance is the official availability of genomic data, particularly for a future employee, insurance company, business partner and/or family.

Patenting living organisms and their parts (from microorganism to human genomic data!) is a complicated issue and conflicting opinions have been presented in this respect (2,7,13,15,16,24). It is important to note, that almost in every country strict restrictions concerning the limitations exist. A patent law applies exclusively on the territory of a particular country, and

the citizens of this country are not limited in their activities on the territories of other states by their own domestic law. For example, a very rigorous new "gene" law and respective restrictions in Germany are not at all limitations for any experiment performed by a German scientist in a 3rd world country (25).

Over the last decade, patenting of animals (13) (excluding humans) and plants (19) has been possible in the USA. In the frame of the new Polish law (23), a patent can be obtained for a chemical formula. We may argue whether a microorganism should be included in this context. According to the German law (8), patent protection can be granted only to those plants or animals (or parts of them) which are essential for further biological processes for production of new plants or animals. There are restrictions in many countries concerning patenting, for example, of medical devices (20).

In France and Great Britain, the genetic fingerprinting analysis is limited to individual cases including criminal cases, testing the family relationships such as fathership and applying for immigrant status. This kind of analysis should be requested by individuals or by authorized government representatives. In Denmark and Great Britain, genomic data analysis cannot be used by a future employee or by an insurance company. In Germany prenatal diagnostic and testing a potential employee for a job through gene sequencing is highly restricted.

Taking a look into the future we should ask a question concerning the responsibility resulting from human genome modification. At first, evidently this is the case of introduction of the genetically modified organism into the environment. Secondly, the consequences of this decision are not limited to a single person, but they will affect generations to follow. The planned, defined change of a single base in the determined gene does not exclude potential modification of another gene, in a far away location. The final effect can be described as a relationship between genetically engineered organism and the environment. A single modification could have some potential influence on the next generation. Today, the effect is unpredictable. We are able to present the experiments performed on animals, or in the *in vitro* system. However, they are far away from the reality of nature. It is extremely difficult to say who has the right to answer these questions and to take the responsibility for the decision. Nevertheless, a very different way of interpretation also has to be presented: Today's genetic engineering technology is not fundamentally different from other techniques, such as crossbreeding of plants; nature has manipulated with genes for millennia.

In relation to the use of genetic information in diagnosis and screening of any kind of working or social group of individuals, people have to have the right of access to the information. Data which may affect people's health or personal and professional life are of particular interest for each individual. The use of information about genetic variability in relation to social security and well-being of human individuals raises basic questions concerning discrimination or classification of people. The confidentiality of these data should be guaranteed on the same basis as the files of medical doctors.

The question concerning the ownership of research data and the regulations referring to the transfer of know-how from science to industry, including transfer outside the country, are strictly connected with the above mentioned problems. We have also to take into consideration the reverse side of the problem: the protective blocking of technology progress by patenting "in advance" of the potential directions of development. "Open" scientific community is the only way to protect pure research against primitive commercialization.

4. Patenting in agriculture and protection of natural genomic resources

A plant variety is eligible for protection if it is characterized by: *distinctiveness, uniformity and stability*. The producer (e.g. a farmer) has the privilege of selling the reproductive plant material of a given plant variety and to save the seeds from the current crop for sowing next season. Protection of a plant breeder's right is fully catered under the Plant Varieties Protection Law (19). The classical technologies of plants and animals breeding are not suitable for modern patent protection. However, the genetic engineering technologies have created a new situation from technological as well as legal points of view.

The starting base for breeding new species or varieties are the already existing varieties. The protected, final variety contains the accumulated advantages of all its predecessors, no matter if they have been created by nature or by man. It is worth noticing that on the market the particular variety differs only incrementally from the others; it is usually only an improved old variety, not at all a "new one": and that is requested to make it eligible for the standard patent protection. In addition, the plant variety protection act (or the patent protection in the case of plant material) protects only the propagating material and not the product(s) obtained from it. This is related to the "farmer's privilege" to retain a portion of the harvest for replanting the next season.

At this *status quo* the discussion concerning the property (ownership) rights to local genetic resources (particularly in the developing countries) has started (12).

According to FAO opinion (25) the genetic resources are the common human heritage of humankind. The genetic resources of the 3rd world countries are essential for genetic diversity and crucial for genetic manipulation and formation of new species and cultivars. The origins of many most important crops (cf. maize, potato) go back to Latin America. Most of the plant genetic material important for industry, nursery and medicinal uses is collected in the so-called Vavilov centers all over the world. These centers are crucial for conservation of plant genetic resources. Unfortunately, much less attention is given to the marine genes collection. In many cases, the plants should not be separated from their natural environment and the collection should

be localized in the place of origin. Commercial use of the resources of the developing countries by giant companies is considered by (some) people as immoral and directed against national interest of these nations. However, to take advantage of these resources high-tech is necessary.

We have to take into account a very different aspect of the protection and securing of the already existing collection of gene banks from natural resources. For example the existing collections in the former Soviet Union are at a very high risk. These collections were started already in the 1920's, by Nikolai Vavilov, and contain millions extremely valuable samples, including unique subtropical species. Relatively little money could protect multi-billion dollars investment. However, because of the shortage of hard currency of the depressed economy and expected privatization of plant and animal breeding the collection may be domaged.

5. Conclusions

In 1991 the FAO Commission on Plant Genetic Resources discussed in Rome (Italy) the forms of compensation for communities and countries who lose markets due to modern biotechnology. One possible solution will be payment by the companies to FAO or United Nations to help preserve the world's genetic resources. Commercial beneficiaries will pay royalties. But tracing of any single gene seems very difficult — no knowledge how to do it is available today!

The United Nations General Assembly stressed the significance of biotechnology for future development (12). Among the indicated matters we can find biotechnology related to human health, agriculture and human well-being. A global system of protection of plant genetic resources, most probably under the auspices of the United Nations, is necessary. We have to take into account the rights of local authorities to the local genomic resources as well as the rights of people to the ownership and knowledge of personal genomic data. The scientists can only produce solid data and people themselves are responsible for their usage. Most experts in the field think that these problems can be solved by refining the existing rules and regulations without preparing novel legislation.

Note added in proof:

Poland signed the Budapest Treaty concerning deposition of microorganism on September 22, 1993. The Polish Depository is located at the Institute of Biotechnology of the Agricultural and Food Industry (02–532 Warszawa, ul. Rakowiecka 36).

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Własność intelektualna w biotechnologii: ochrona naturalnych zasobów genomowych oraz własność danych genetycznych

Streszczenie

Prawa własności intelektualnej chronione przez patenty, prawa autorskie czy nawet „sekrety firmy" nie wyjaśniają problemów związanych z własnością danych analitycznych pozyskiwanych z zastosowaniem nowoczesnych technik analizy genomu człowieka czy też nie zabezpieczają kwestii własności naturalnych zasobów genetycznych. Ilustracje z aktualnych prac badawczych i działań politycznych w skali międzynarodowej ilustrują znaczenie tych kwestii, zarówno w aspekcie moralnym jak i ekonomicznym. Zagadnienia te są przedstawione w artykule, aczkolwiek obecny stan prawny uniemożliwia przedstawienie konstruktywnych rozwiązań.

Key words:
genomic resources, genomic data, intellectual property in biotechnology.

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