

EDITORIAL

BIOETHICS, INTELLECTUAL PROPERTY AND GENOMICS

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RHCFAP/3043

SEGRE M et al. - Bioethics, Intellectual Property and Genomics. *Rev. Hosp. Clín. Fac. Med. S. Paulo* 56(4):97-102, 2001.

Scientific and technological advances will never be anti-ethical. For mankind, “a search for new ways” means better conditions for achieving autonomy. Everything that has been discovered in the last few decades, from how to control the birth rate, to the recent probability of being able to clone human beings, and, within these latest discoveries, the extraordinary possibility of manipulating the human gene itself, empowers us to assume control of what until now was unknown, and thus we will be able to attain a better quality of life.

With respect to the ideal, it is unquestionable that the knowledge that could substantially change our lives on this planet should be within reach of the world society; society itself should be responsible for monitoring the applications of this knowledge.

The present article discusses the ethics and the patenting of the human genome, arguments for and against gene patenting, patents and research into human embryos, legal aspects, and intellectual property in the field of the human genome.

DESCRIPTORS: Bioethics. Genomics. Human Rights. Patenting. Intellectual Property.

Scientific and technological advances will never be anti-ethical. For mankind, “a search for new ways” means better conditions for achieving autonomy. Everything that has been discovered in the last few decades, from how to control the birth rate, to the recent probability of being able to clone human beings, and, within these latest discoveries, the extraordinary possibility of manipulating the human gene itself, empowers us to assume control of what until now, was unknown, and thus we will be able to attain a better quality of life.

The fear, which is understandable, regarding what is going to happen the moment we modify our habitat and ourselves is founded on the fear of the unknown. We live with tragedies, such as wars, oppressions, inequalities of

every type, affronts to human dignity at all levels, diseases, etc., but the moment we are told “Man is playing of God”, many of us belittle ourselves without debating the issue. We forget that man has played this game for all of recorded history, and that if it were not for this game, we would not have won the battle against so many diseases—a victory that has prolonged life expectation for decades, reduced infant mortality, etc .

What could be frightening is the way in which we apply the new knowledge, which could be used for discrimination, oppression, and extermination,

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as so many other advances in knowledge have been used. It could be said to those who condemn and abhor the discovery of nuclear energy that, considered on its own merit, this advancement in knowledge was an enormous success for science; what we condemn was its use in killing millions of human beings. We must remember that a treaty of non-proliferation of nuclear weapons was drawn up and signed and that, up to the present time, it has been respected; therefore, it is clear that we are (or, if not, should be), capable of responsibly administering the application of new techniques with the intent of applying them in ways that are compatible to our sense of ethics. Therefore, since we accept that knowledge will never be ethical or anti-ethical *a priori*, we will not raise

objections to the freedom of developing this new knowledge.

It is an ideal (utopian, while at the same time ideal) that knowledge that could substantially change our lives on this planet—and change the planet itself—should be totally acceptable to the world society; society itself should be responsible for monitoring the applications of this knowledge. We can say that through the branch of the United Nations Organization (UNO), which is directed to health and education (United Nations Educational, Scientific and Cultural Organization - UNESCO), world society embraces this ideal—at least in theory.

The acceptance or not of patenting knowledge, the experimental application of this knowledge, the application of new techniques on a wider scale, or the question as who might develop these techniques (private enterprises, government enterprises, or others)¹ is something that must be discussed. It is perfectly understandable, for example, to accept that a certain laboratory may patent its research (at least for a finite period) as long as the patent does not impede other research laboratories from applying the techniques resulting from these studies towards applications that might benefit humanity.

ARGUMENTS FOR AND AGAINST GENE PATENTS

The question of gene patenting involves several different fields (economic, philosophical, religious, etc.), and as a result, a varied number of arguments with respect to it arise. Some of these arguments are presented here.

Among those who defend gene patents are those who wish to offer a reward to the researcher, who, like other workers, should be able to reap the benefits of their work. Thus, in return for the time, energy, and resources spent on their work, a patent should be

given in compensation. The argument against this position is that after considering the market value of these patents, it is reasonable to conclude that they provide a much greater benefit than the owner deserves. The majority of innovations can be attributed to the scientific predecessors of biotechnologists, such as Darwin and Mendel. To say that a researcher is responsible for the total value of the organism or gene modified is like saying that the last person called to help lift up a car should receive all the credit for lifting it.

Moreover, it should not be forgotten that a large part of biological research that eventually leads to the distribution of private patents is financed by public resources. It is common knowledge that every inventor needs to use natural products and pre-existing components, and at the same time it is very clear that all inventors rely on their predecessors. One of the most common arguments in favor of biopatents is their great social utility, which surpasses any other consideration. Biopatents serve as a necessary incentive to encourage and support innovations. Without them, competitors would prefer to let others innovate, so they can copy the final product and sell it for a lower price than the innovator can, since they would not have to pay the cost of research and development.

A possible argument against patents is that the process of transferring biological knowledge into private knowledge threatens the continuance of scientific cooperation, and slows down the rate of innovations. Moreover, businesses uniting universities and industries result in secrecy in university laboratories and a growing amount of skepticism in relation to the value of exchanging information among colleagues. The counter argument is that patents do not hinder pure scientific research, since any scientific use of the invention patented does not constitute a violation of the patent.

Apart from this, experience has proved that an effective transfer of technology from laboratories to industries can only be done by way of an active and effective policy of patenting and licensing.

Contrary to the argument for confidentiality of research, it can be pointed out that upon submitting applications for patenting (at least in Europe), secrecy is not guaranteed. On the contrary, by submitting these applications, an immediate publication of the invention is permitted. In addition, it should not be forgotten that a common practice among scientists in this area is of not sharing the results of their research until their papers have been published (this is not so very different from the practice of patenting).

Another argument in favor of patents is that if they were abolished, people would seek other ways to protect their innovations, resulting in the keeping of commercial secrets, which, in relation to accessing information, is much worse than patenting. Applications for patents demand the revelation of the technology involved, while the protection of industrial secrets does not require this disclosure.

Among those against patenting, there are those who argue that patents impede progress: they serve as incentives for firms to invest resources in the development and protection of patents—resources that could be used in investments for inventions and innovations. Additionally, they argue, the existence of patents could result in the elimination of competition in the industrial field. Opponents of patents argue that biopatents pose a moral danger; they support social politics that continues to encourage the human tradition of domination, decision-making, and manipulation of nature instead of helping the population become equal members and citizens of the planet.

In discussing the question of biopatents, it is also important to consider the potential ecological damage that

could appear as a result of the introduction of artificial genes into the environment. For example, by producing plants resistant to chemical pest controls, a new and dangerous dimension is introduced into the ecological system that could change the balance of nature and damage the fertility of the soil. However, these misgivings tend not to overshadow the clear advantages of biotechnology, nor do they warrant the rejection of the idea of patenting genes.

Another point to be considered concerns biological colonialism. By assuming that human tissue is a natural resource, like iron and oil, researchers could look for “exotic” genes from remote civilizations—genes that could serve as raw material for a new and lucrative type of medical practice. This practice could result in exploitation of indigenous races—which are considered primitive by the western world—without giving them any part of the profits. This practice would amount to exploitation of developing countries (abundant sources of genetic resources) by developed countries.

Another aspect for consideration is the patenting of genetically modified plants and animals. One of the problems in this context is: what is the total number of human genes that would have to be “transplanted” to an animal for it to be considered “human” or animal genes to a human for it to be considered an “animal”? In view of the fact that today patents are given for genetically modified animals that carry human genes, will patenting of human-animal hybrids be permitted? Here the fear of creating genetically modified monsters arises. Thus opponents of biopatents argue that scientists should not be encouraged by the system of patenting to create half-human beings.

Elitist ideas have been related to genetic research, inevitably raising issues such as racism, due mainly to the fact that historically some geneticists believed that characteristics such as in-

telligence and integrity were connected to the genetic structure, which consequently determined the social status of man. The role of “playing God” produces the danger of treating animals and human beings as simply tools for research. In addition, if one considers the argument of the “snowball” effect, as soon as the knowledge of how to control and manipulate human responses and to create human hybrids exists, there is the risk that experiments without any scientific value will be performed. However, by being taken to the extreme, this argument ignores the fact that there is strict government supervision and control, prohibiting cruelty and limiting experiments.

Following are some other considerations relating to the issue:

Arguments in favor of patenting:

- Genetic patenting is only a logical extension of the traditional use of patents and does not represent great changes (Raines).

- One should comprehend patenting of animal and human genes in its correct historical and economical context. Thus, as man has always dominated the animal kingdom (selling and buying animals and raising animals in the home); patenting their genetic material is part of the process (Raines).

- There exists the natural right for man to be recompensed for the fruits of his labor, an argument used in favor of property rights in general, and derived from the theory of John Locke, which originally stated: “I made it, I created it, it is mine; it would not exist without me.”

- Live organisms such as plants and microorganisms do not have moral interests that need to be taken into account (Joel Finberg).

- Genes, cells, and other parts of the organisms are artefacts in relation to live organisms; therefore, there should not be any conceptual difficulties in relation to them, since they are not in-

involved in moral questions (Schonmann).

- Any alteration, isolation, or purification of a substance or organism from their natural state transforms them into something else that is not “found in nature,” and therefore is patentable (in the USA genes are patentable when isolated and inserted with other DNA into a cell) (Schonmann).

Arguments against patenting:

- It is irrational for society to guarantee the right of monopolizing something that everybody could use (Hettinger).

- Patents and their market value are a social phenomenon created by the judicial system and also by mechanisms of supply and demand. The researcher did not invent the gene that is to be patented, nor did he generate its market value; hence, he does not have a natural right over it (Schonmann).

- Any mixture of something from one person with something that is not from that person does not mean that the person is the “owner” of the mixture. For example, a DNA molecule injected into another organism (Robert Nozick).

- Biocentrism theory: All creatures possess moral interests that need to be considered and respected. Always, when determining what people can do with organisms one should consider the moral aspect, and take into consideration the interest of the organism to be obtained, even though it has been raised by man or genetically manipulated (Albert Schweitzer).

- The patenting of genetic material creates a fixed and distorted moral perception with respect to our relationship with organisms, which inevitably leads to a depreciation of the value of life.

- All creatures that can feel pleasure and pain have moral interests to be considered; therefore, genetically altered animals should not be treated as mere research objects (Peter Singer).

- The relation between genes and the different organisms in which they have been inserted is inseparable. The genetic manipulations that are carried out in an organism depend on the organism, and consequently its moral questions (Schonmann).

- Genetic material contains 3.5 billion years of information relating to human evolution, which lead to a developed life form, therefore the genetic information belongs to everybody as an inheritance and cannot be patented (Hettinger).

- Genes were created naturally and are not human inventions; they are only discovered by research and are not patentable (Hettinger).

PATENTS AND EMBRYONIC RESEARCH

Cloned human embryos do not have legal personalities, and at least in theory, are viewed as cloned cellular strains. Thus, could an embryo be classified within the legal prerequisites for patenting, and as such be patented, reproduced, and sold? A preliminary question would be: Should scientific research with human embryos be permitted and could animal models serve as substitutes? There are those who defend the analysis of embryonic genetic expression and its standards in order to understand human development. The legal personality of embryos must be debated, since society today has no accepted definitions with respect to the moral and legal status of frozen embryos.

On the one hand, a human embryo is a powerful symbol of humanity that must be respected. On the other hand, experiments with embryos would benefit millions of people. Thought should be given as to whether human dignity is maintained in the process of producing genetically predetermined babies. Embryos are actually potential people

and must receive the highest moral valuation; any attempt to consider them patentable would be an insult and morally questionable. But, on the other hand, any embryo outside of the uterus is not a potential person, just as an ovum and a spermatozoon are not potential people, because they are incapable of developing alone. However, as their development progresses and they become more and more similar to an entity that possesses moral status, they stimulate our wish to protect them.

The patenting of genes is both an ethical and a moral problem. Intuitively, many people reject the practice of genetic experiments on animals and humans (even more so the patenting of them), but when analyzing this question in a more realistic way, we must remember that at least some genetic techniques have been developed and established and have not raised any great objections.

The language of the different patent laws has originated from inventions in physics and chemistry, and maybe it would be preferable to create a system of protection more compatible with biological inventions. On verifying biopatents, it seems that intellectual property rights are implicated; however, there is still a great deal of confusion as to whether or not genes are property and to whom they belong. These questions can no longer be ignored.

None of the arguments prevail over the rest, especially when some have mystical-religious bases that cannot be refuted. This subject also involves not only rational explanations but also emotional ones, which leads to complications. It is important to emphasize that even if patenting genes is allowed, doing whatever one wants to is not permitted. A patent by definition implies what could be thought of as a "negative" right, meaning the exclusion of others from using the patent. Additional restrictions relating to the person

applying for a patent would be interesting, especially in cases of possible lethal or suicidal genes.

The progress and development of scientific research requires a flexible legislation, which could include this new material. The majority of questions on this subject continue to be unanswered, raising ethical and moral dilemmas that are not easily resolved, just as they raise philosophical and intuitive considerations.²

UNESCO

UNESCO is one of the first international Organizations to have tried working with bioethics. The Universal Declaration of the Human Genome and Human Rights, adopted unanimously and applauded at the General Conference of UNESCO in November, 1997 is one of the major achievements of such efforts. The Declaration was endorsed by the United Nations General Assembly in December, 1998, within the context of the 50th anniversary celebration of the Universal Declaration of Human Rights.

Drawn up by the International Bioethics Committee of UNESCO (founded in 1993), the Universal Declaration of the Human Genome and Human Rights is the first international standard in the field of bioethics. Article 1 states that the human genome is the "inheritance of humanity." The idea is to emphasize the fact that research on the human genome and the applications that could stem from such research is the responsibility of humanity as a whole, in the interests of present and future generations. The expression "the shared inheritance of humanity," which was initially proposed, was subsequently changed to "the inheritance of humanity," so as to avoid any interpretation that could possibly leave the human genome open to collective, individual, or private appropriation.

This obviously leads to ruling out human genome patentability. Article 4 of the Declaration confirms this assertion, by stating:

“The human genome in its natural state shall not give rise to financial gains.”

UNESCO, in accordance with its calling to further the sharing of knowledge, feels that the fact of knowing of a human gene or its partial sequences in its natural state cannot be the object of intellectual property rights, and that this knowledge must be freely accessible to all those involved in research world-wide. This does not rule out the fact that the results of research may be covered by intellectual property rights.

The Declaration also contains provisions for scientific cooperation. Under Article 18, member states are urged to make every effort “to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity, and genetic research (...) particularly between industrialized and developing countries.” Article 19 invites member states to take measures enabling “developing countries to benefit from the

achievements of scientific and technological research, and foster the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine”³.

BRAZILIAN LEGISLATION

Section III – Of the inventions and utility models that are non-patentable.

Art .18 What are not non-patentable:

I - all that is contrary to ethics, to good customs and to security, public order and health;

II - the substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties, and the respective processes for obtaining or modifying them, when they are the results of atomic nucleus transformation; and

III - all or part of living beings, with the exception of genetically modified micro-organisms which fulfill the three requisites for patentability – novelty, creative activity and industrial application - foreseen in art 8 and, which are not mere discoveries.

Singular paragraph: In accordance with this law, genetically modified micro-organisms are organisms, except all or part of plants or animals which express, through direct human intervention in their genetic composition, a characteristic not normally attainable by the species in natural conditions⁴.

In the face of the incipient nature of this research - Brazil has a modest role, giving its contribution through the Human Cancer Genome Project and by the sequencing of a farm pest (*Xylella fastidiosa*) - Brazilian law is poor in this sense. Apart from this consideration, Brazilian law is very restrictive. For this reason, efforts by bioethicists, legislators, and jurists have become imperative. In this new era, the inadequacy and restriction of our legislation calls for the Brazilian Society of Bioethics and the National Technical Commission for Bio-security (CTNBio)⁵ to work together in order to monitor and apply ethical values, while at the same time taking care not to create obstacles with respect to the growth of what we believe could contribute to the development of the “quality of life” on the planet.

RESUMO

FHCFAP/3043

SEGRE M e col. - Bioética, Propriedade Intelectual e Genômica. **Rev. Hosp. Clín. Fac. Med. S. Paulo** 56(4): 97-102, 2001.

O avanço científico e tecnológico nunca será anti-ético. Ao menos, enquanto considerarmos que “a busca de novos caminhos” para o Homem, significa condição melhor dele ter autonomia. Tudo o que se vem descobrindo nas últimas décadas, desde o controle da natalidade, até a probabilidade de se realizar brevemente a clonagem de se-

res humanos, incluindo-se entre estas últimas descobertas a extraordinária possibilidade de se intervir no próprio gene humano, representa a condição de assumirmos nós mesmos o controle daquilo que até então desconhecíamos, e, assim, poderemos alcançar uma qualidade de vida melhor.

Quanto ao ideal, este inquestionavelmente é o de estarem, os conhecimentos que podem alterar substancialmente nossa vida no planeta, ao alcance pleno da sociedade mundial, caben-

do a ela o monitoramento da aplicação desses conhecimentos.

O presente artigo discute a ética e o patenteamento do genoma humano, os argumentos a favor e contra o patenteamento de genes, patentes e pesquisas com embriões humanos, aspectos legais e propriedade intelectual no campo do genoma humano.

DESCRITORES: Bioética. Genoma. Direitos Humanos. Patenteamento. Propriedade Intelectual.

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Received for publication on March 19, 2001.