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LEGISLATIVE APPROACHES OF THE BEGINING OF HUMAN LIFE AND PATENT ON HUMAN DNA

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ABSTRACT

There is no consensus on the matter and it determines the fact that international law avoids to specify and define the exact of beginning of human life and indicate the date by which the right to life is acquired - only after birth or it belongs to unborn human being too. International courts also do not provide a specific answer therefore in different countries the issues of beginning of life are regulated differently. World patent system is based on the main characteristics of patenting, i.e., inventions must meet the general details – invention novelty, utility and nonobviousness. In addition, it is important to comply with the requirements to public orde and morality, which are becoming essential on isolated human genes and cells patenting. Moral and Ethical issues in Europe and the U.S. are different scope. According to the European system, the question of when morality may be used as a basis to exclude patents on biotechnological inventions is an ethical question and also closely interconnected with fundamental constitutional issues. It must be kept in mind that Community law is premised on recognition and respect for diversity of moral traditions and culture in Europe. U.S. takes fully cardinal position than EU and focuses on technical inventions requirements: novelty, non-obviousness, and utility. Moral issues are not significant. This practice is formed the U.S. judicial system, which is based on the principle of public utility.

Key words: Genes, Legislation, Patents.

INTRODUCTION

In the view of a rapid development of science, the emergence of various new technologies such as artificial insemination, prenatal diagnostics, the appliance of embryonic stem cells which is related to human life, the regulation of protection of human genetic data becomes very important. And this regulation should ensure the protection of life from the very beginning, however the main issue- the disagreement of when life begins- arises both on international and national level. Process in biotechnology, new innovative ideas in medicine, research in biomedicine field showed their tremendous potential treating, until now, incurable diseases. However, the human stem cells are understood as a formula, able to make a revolution in the field of the medicine. Although, the potencial carried by cells confronts the moral, ethical and legal oppositions, which state that human stem cells should not be the objects of the patent. It is important to analyse the conception of isolated human genes and cells, and the main importance is given to the analysis of legal international, regional and local laws in Europe and the USA, which regulate the status of isolated human genes and cells in connection with the patent laws.There exist two types of requirements for patentability: novelty; morality and dignity. These requirements constrains depend on each and every countries‘positions [1-5]. The international patent law sets the main task to harmonize the basic technical things among the countries.

Human genome and identify genes led to the establishment of the Human Genome Project (HBP) . The HGP estimates that the human genome consists of 20,000 to 25,000 genes [3-6]. The US Patent and Trademark Office (USPTO) issues thousands of patents for human genes identified by HGP and it is reasonable to believe that this trend will continue as the HGP isolates and identifies

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more human genes. This increase is not only evident in the United States, but also and in the EU.

Deoxyribonucleic acid (DNA) is a molecule that encodes the genetic instructions used in the development and functioning of all known living organisms and many viruses. DNA is well-suited for biological information storage. The DNA backbone is resistant to cleavage, and both strands of the double-stranded structure store the same biological information. The U.S. Supreme Court in the case of the Association for Molecular Pathology vs. Myriad Genetics, held that naturally isolated DNA is not patentable, but that synthetic DNA is patentable. The Court held that isolated human genes cannot be patented because it is not a product of nature, and not man-made and specific gene separation from the rest of the genetic material is not a sufficient condition for the patenting [5-9]. Professor Watson makes the argument that „human genes should not be patented because DNA is a unique molecule different from other chemicals and should be treated as such“ . Association for Molecular Pathology v. Myriad Genetics says that corporate efforts to appropriate the human DNA is not only unethical but also unfounded becouse isolated gene is not created by human . To answer the question, „Are human genes patentable?“ The Supreme Court decision was focused on the “product of nature“ exception. The Court indicates that artificial coping method designed synthetic DNA sequences can be considered as intellectual property because it is not natural.

MATERIALS AND METHODS

The aim of the study was to compare the U.S and European patent systems.

RESULTS AND DISCUSSION

The U.S. patent system is recognized as being the broadest patent protection system, especially in the biotechnology field. U.S. patent law arises from the U.S. Constitution. The product for which the patent is being sought must meet stated levels of novelty, utility, and nonobviousness . The statutory patentability requirements are applied to biotechnology, including DNA sequences, in the same way as they are to any invetion. However, there are still many individuals who believe that DNAsequences do not satisfy the base requirements for patentability - utility, novelty, and nonobviousness. In Europe the argument is that DNA sequences should not be granted patent protection because this violates order public or morality, relying on the Directive and the EPC [7-10].

The other very important subject is Human Cells. Cells can establish a new kind of reparative medicine - treatment using stem cells. The U.S. National Insitutes of Health defined regenerative medicine as „the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenitial defects“. Many of these processes involve the use of stem cells. Stem cells are undifferentiated biological cells that can differentiate into specialized cells and can divide (through mitosis) to produce more stem cells. There are two broad types of stem cells: embryonic stem cells, which are isolated from the inner cell mass of blastocysts, and adult stem cells, which are found in various tissues [9-14].

Some of the fundamental patents covering human embryonic stem cells are owned by the Wisconsin Alumni Research Foundation (WARF) - they are patents 5,843,780, 6,200,806, and 7,029,913 invented by James A. Thomson. WARF does not enforce these patents against academic scientists, but does enforce them against companies. In 2006, a request for the US Patent and Trademark Office (USPTO) to re-examine the three patents was filed by the Public Patent Foundation on behalf of its client, the non-profit patent-watchdog group Consumer Watchdog (formerly the Foundation for Taxpayer and Consumer Rights).

James Thomson, who worked at the University of Wisconsin, was one of the first who identified human embryonic stem cells. University of Wisconsin filed an application to obtain a patent. In 2001 the University became entitled to a broad scope of patent protection granted by the U.S. Patent to the holder and University of Wisconsin, gave the right to request that „no one person, organization, or any other entity in U.S. cannot distinguish, to use, sell or import cells from other countries until to 2015“ . U.S. patent and Trademark Office granted the patent, because it complied with the technical requirements of inventions. Attention has not been given to the moral norms dimension. Therefore, the patent law should not become a moral law, even in terms of biotechnological inventions. However, based on the principle that the granted patent may be voidable the University of Wisconsin patent to the other two patents was appealed by the two stakeholders Taxpayers and consumers Rights Fund (the Foundation for Taxpayer and Consumer Rights) then replacing its name to the Watchdog and the Public Patent Foundation (called the Public Patent Foundation). The invention according to Jeanne Loring (one of the stem cell researchers from the Burnham Institute of Medical Research), did not meet the criteria for novelty because „the real invention has been implemented 25 years ago (1981) since scientists Martin Evans, Matt Kaufman, and Gail Martin discovered animal stem cells, but did not seek to obtain a patent for the invention“ . The second argument is perceived the main aspect of the invention and their application possibilities. The third reason for the damage was that patented human embryonic stem cells law has made it impossible to carry them any research whereas, in order to carry out research, it was necessary to buy a permit.

Critics say „research on embryonic cells is immoral...“. EU Directive (1998) clearly forbids patents on the industrial use of human embryos, yet industry has tried time and again to push them through. German Green MEP

Hiltrud Breyer, who is also president of the European Parliament Bioethics Intergroup, "wholeheartedly" welcomed the "landmark ruling", saying that "human dignity has rightfully been put first". WARF said „it was considering various responses and stressed that the decision would not affect patent rights in the US".

However, there is not one of the patent system in this world. The validities of patents, generally applicable rules and policies, in relation to patents of the states, varies depending on the specific standards or rules. Therefore, it is necessary to remember the Convention on Human Rights and Biomedicine there in the article 2 is said „The interests and welfare of the human being shall prevail over the sole interest of society or science" . As noted, in its essence, the Convention alive in the old continent of Europe in two main documents regulating biotechnology inventions status, i.e. European Patent Convention (EPC) , adopted in 1973 and Directive of the legal protection of biotechnological inventions (EU Directive), adopted in 1998 . To talk about this legislation is important because in 1999 EPO Administrative Council incorporated the individual articles of the EU Directive on the EPC to harmonize patent issuance policies in Europe. Therefore, the EPC and the European Directive regulates the scope of the law of human embryonic stem cells in Europe. There is stressed in EU Directive that „Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive". The latter provision implies uniform rules of lawmaking ambition in patent law at regional level [8].

EU Directive individual articles are identified potential inventions, i.e. biological material (EU Directive art.2, part.2), a way and a method which makes it possible to get the material to the specific features. All these inventions are recognized as patentable if they meet the general requirements of patentability - . However, although the biological material or a particular way will be recognized as inventions they can get to the list of unpatentable objects, enshrined in EU Directive and in few EPC articles. These documentations provide that „the human body cannot constitute patentable inventions, an element isolated from the human body or a partial sequence of a gene". Unpatentable are „processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals" . Moreover, bearing in mind that patents are mostly acquired for the economic benefit of the invention, possible to state that pliuripotencial human embryonic stem cell patenting is not possible [8]. The EU Directive article 5, second paragraph, says that: „An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element". This article is caused by objections in many countries. This is contrary to the same article 5, par. 1. European Court of Justice pointed out that isolated human embryonic stem cells, except totipotencial human embryonic stem cells, is patentable inventions, because they are identified in the technical process and is identical to human cells of the embryo [5,11].

In the EU Directive, article 6, unpatentable invention includes the use of human embryos for industrial and commercial purposes. This is a handy rule of law protecting pliuripotencialias human embryonic stem cells from patentability if the patent would be used for commercial purposes. EU Member States could not decide what it should be identified as violating public orde. EU countries were not satisfied with the final adoption of a legal instrument for human embryonic stem cells because there have been left unresolved questions. Most discussions were about moral issues enshrined in Article 6, par. 2, of the EU Directive where the unpatentability were identified human embryous. However, this Directive has been implemented in the EU in June, 2006. It should be noted that, the morality clause content contained in Europe, is not always directly reflected in the national legal systems of the Members, which has an autonomy freedom, determining the scope of morality.

Germany is one of the countries, which expanded the scope of unpatentability. One of the most radical states in the continental legal system is Germany with the strictest laws on human embryonic stem cells in the entire world. One of the German scientists, Oliver Brüstle has gained the patent for nerve cells extraction method from human embryonic. However, the decision to issue the patent received negative assessments and the requirement to eliminate that patent. One of the initiators of the revocation of a patent, Christoph Then, noting thatpersons seeking to obtain patent protection throughout that sees business opportunities, but „the commercial use of human embryos is forbidden" . The Court ruled that anyone extracted from human or human tissue cannot be patented. The court held that the object for which the patent was granted objected to the public order and morality ideas. The court wanted to show that morally controversial steps must be cancelled regardless of the fact that there were no provisions providing a moral clause in respect of certain objects [8].

Comparing US and European legislative and judicial approaches to the grant of patents on isolated human genes and cells, in the author point of view the worldwide general patentability details are similar and its content reflects nearly the same characteristics of patentability, differs only the word identification of particulars. The main and the biggest difference is noticeable in the moral and ethical patent ability assessments, there is a difference between general and civil law in countries. United States, as belonging to the first

group fall into the sphere of moral neutrality. The author believes that the Europe patent legal system is more appropriate for its approach to human morality and dignity. Human is valuable in itself, created by nature. There are other ways and methods to heal the human being or disease, not only patenting inventions, which supposedly created by human diseases. U.S. does not give importance to the morality and focuses on the economy and social welfare by allowing people to get well in this way, not making any reservations to the patenting of human stem cell. It should be respected the fundamental human, embryo, isolated human gene rights and freedom. In the Convention on Human Rights and Biomedicine is published an important provision that countries of the Convention protect all human dignity and identity and without discrimination, ensure respect for everyone's integrity and other rights and fundamental freedoms in biology and medicine fields [8].

CONCLUSIONS

Comparing biotech innovation and protection of isolated human genes and cells between Europe and the U.S., the United States should to consider interpreting patent laws more rigidly. Human DNA is not only unethical but also unfounded because isolated human gene is not created by human. Protective zone is also determined to the human embryonic stem cells, arguing that inventions are unpatentable when embryos are used for commercial or industrial purposes and if this is contrary to the order public and morality. The University of Wisconsin challenge the granted patent showed the moral clause is still alive in Europe, while in the case of the United States challenged the patent gave a solid foundation to doubt that granting of a patent in the United States, based only on technical criteria, will be revised in the near future.

Patents, which may violate imperative provisions of the legislation or do not meet the expectations of the public, are not granted and if they were granted of first implemented inventions years, they are challenged by stakeholders as violating societal norms, it does not matter it is ethical, moral, social, or economic.

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CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest.

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