GENERAL REVIEW OF THE NEW OBJECT OF PATENT LAW WHICH CORRELATES TO THE NEW BIOLOGICAL WEAPON AND RELATING TO PHARMACOGENOMICS

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In today's highly technological world, biotechnology is one of the most innovative and highly invested in industries for research, in the field of science. Since the researcher in pharmacogenomics has been given the promise to create personalized treatment and drugs for patients suffering from many common diseases, particularly those with multiple treatment modalities [1], the issue about the legal status of inventions in the field of pharmacogenomics and criteria of patentability for them becomes one of the most important to be solved at the beginning of pharmacogenomics era.

The research results of the pharmacogenomics gradually assuming an important part in clinical practice in deve-
developed countries and becomes the main subject for research for pharmaceutical companies. As a rule the world biggest’s pharmaceutical companies are interested to invest money to pharmacogenomic’s research and involving such results to produce “personalized” drugs in the practice.

The prospect of acquiring exclusive rights for inventions, which are based on the establishment of certain medicines to treat a wide range of health problems, including cardiovascular disease, Alzheimer’s disease, cancer, HIV / AIDS and asthma, which are provided by patent protection is a strong incentive for pharmaceutical companies to develop research in pharmacogenomic [2].

That is why being able to secure the intellectual property in pharmacogenomics research is vital to attracting investment, protection innovations, and fostering the success of companies with leading technologies.

Patent availability nowadays on the one hand is the main instrument for protecting investments, and guaranteed earnings for pharmaceutical companies what provides the investments to new researches. Although, on the other hand, patents in the pharmaceutical and pharmacogenomics areas are legal instrument for manipulate categories such a health and sickness, life or death depending of the material wealth individuals.

The question of compliance with the conditions of patentability to inventions in pharmacogenomic including general questions of the patentability of the inventions, additionally correlates the possibility of obtaining a patent for an invention that uses human genes, the issues of morality and public order, and concerns the use of the results of pharmacogenomic as weapons of bioterrorism.

The issue of the use of the results of pharmacogenomic as bioterroristic weapons was one of the main subject of the research work during the research stay at the University of the Basque Country (Bilbao, Spain), within the framework of the Project «Bioterrorism and Biosecurity: Basis to structure new penal instruments to face the biological threats» (funded by the Spanish Ministry of Economy and Competitiveness MINECO and developed at the University of the Basque Country). Project Reference Number: DER2014-56634-JIN.

1. **The main principles of pharmacogenomics**

The year 2000 is marked by the production of the sequence of the human genome. A ‘working draft’ of high quality sequence covering 90 % of the genome has been determined and a quarter is in finished form, including the first two completed chromosomes [3].

Since the scientific world had gotten the ability to undertake DNA sequencing on a large scale been started a revolution in biology, which gave the possiblity to determine the complete DNA sequence of any organism and therefore obtain a full description of genes and other important biological information stored in the genome. For the first time, it has been possible to define the complete set of proteins required for a particular life form, made full comparisons of protein sets between different species, to discover the basis of their similarities and differences and to explore the evolutionary relationship between them, what had led to been granted a thousand of patent related to inventions based on genetic material [4].

Some of these patents constitute important intellectual property assets for companies dedicated to the translation of biomedical research findings into diagnostic agents and life-saving therapies.

In general pharmacogenomics is the study of how genes affect a person’s response to drugs. This relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that will be tailored to a person’s genetic makeup.

For better understand what role do genes play in how medicines work, how is pharmacogenomics affecting drug design, development and prescribing guide-
lines and what exactly can get patent protection, below we describe in general principles of pharmacogenomics.

One example involves a liver enzyme known as CYP2D6. This enzyme acts on a quarter of all prescription drugs, including the painkiller codeine, which it converts into the drug’s active form, morphine. The CYP2D6 gene exists in more than 160 different versions, many of which vary by only a single difference in their DNA sequence, although some have larger changes. The majority of these variants don’t affect drug responses. Some people have hundreds or even thousands of copies of the CYP2D6 gene (typically, people have two copies of each gene). Those with extra copies of this gene manufacture an overabundance of CYP2D6 enzyme molecules and metabolize the drug very rapidly. As a result, codeine may be converted to morphine so quickly and completely that a standard dose of the drug can be an overdose. On the other end of the spectrum, some variants of CYP2D6 result is a nonfunctional enzyme. People with these variants metabolize codeine slowly, if at all, so they might not experience much pain relief. For these people, doctors might prescribe a different type of pain reliever [4].

2. Personalized medicine

Would a teenage boy buy the same clothes as his grandmother? Probably not. But when they get sick, they’re likely to receive the same medical treatment, despite their many differences. And so will everyone else [5].

The result is a «one-size-fits-all» approach to medicine that is based on broad population averages. This traditional practice often misses its mark because each person’s genetic makeup is slightly different from everyone else’s, often in very important ways that affect health.

That is why, today, the pharmaceuticals company focused on the development of personalized medicine and on pharmacogenomics — technology which is widely held to be central to future pharmaceutical development and health-care — hold genetic patents as essential to securing the revenues necessary to introduce these products to the market.

This approach opens up entirely new opportunities, for treatment of any level of known and new diseases, but also brings a new complicated legal and moral questions related to patent protection for such innovative drugs and diagnostics methods and the most important questions about legal regulation perspective to create personalized biological weapon.

3. Patent and pharmacogenomics invention

A patent is a legal title that can be granted for any invention having a technical character provided that it is new, involves an ‘inventive step’, and is susceptible to industrial application. A patent can cover how things work, what they do, what they are made of and how they are made. According to the Ukrainian Law “On Protection of Rights to Inventions and Utility Models” [6], object of invention can be:

• product (device, substance, culture of a microorganism, culture of cells of plants and animals, etc);
• process (method);
• new application of the already known product or process.

Given the big financial issues, which came from investment to develop personalised medicine (aside from the benefits to patients), where is the benefit to the pharma industry? Given that research is expensive and the markets for personalised medicine are, by definition, smaller, — this is the main question the answer to which lies in the benefits of patent granted.

The patent grants legal title holders the right to prevent others from making, using, selling, offering for sale, or importing an invention without his consent. It only confers these exclusive rights for a limited period (in Ukraine and Europe, 20 years from filing) and for a limited geographic territory, in principle the territory of the state in or for which it is granted.
In general the patent should produce benefit for society beyond the inventor. This is linked to one of the criteria for awarding a patent, utility. Article 27 of the Universal Declaration of Human Rights states that everyone has the right ‘to share in scientific advancement and its benefits’. This is a general criterion, not specific for pharmacogenomics and gene patents, but is the argument that often used in the patent debates to support IPRs for gene patents. Although in the part 2 of Article 27 mentioned that «Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author» [7].

However, in a case of pharmacogenomic invention there are suggested that patent protecting may even inhibiting researching by the discouraging investment into areas where already are many broad patents [8], and still there is no strict opinion about patentability requirements to genome patents.

The legal system of intellectual property today is one of the most sensitive to the dynamics of development science in society, that is why the legal system is in a state of continuous improvement principles and methods of legal regulation of newly created objects.

For example, the morality criteria of patents and the system to enforce them has become one of the most controversial aspects of biotechnology, which has not been a such required for early patenting on medical products of biotechnology, such as insulin [9], and early genetic engineering techniques, although always was the main principle for patenting.

But of all the areas of modern science and technology that involve intellectual property protection, patenting of biotechnology inventions, and specifically genes and pharmacogenomics, as it has been mentioned earlier, prognosed to create a personalised medicine and drugs, has captured the greatest public attention and controversy under the issue of patentability criteria.

According to the favored definition, pharmacogenomics patent is as a reference to a specific and isolated genetic sequence, its chemical composition, the process used to obtain or use it, or a combination of these. What is more, the patentability of natural genetic sequences is not unanimous, and patents on genes have been allowed only in regard to isolated gene sequences with well-known purposes, and not for those naturally present in human beings or other living organism.

So the pharmacogenomics patent may be understood as that relative to a product or process which include the single, specific human gene sequence, which may be natural or synthetic, creates in a laboratory through biotechnology (even if it based on a natural human genetic sequence). The patents for pharmacogenomics include claims for genomic DNA sequences, complementary DNAs, [10] individual mutations, expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs) [11].

4. Legal regulation

The main legal act which provide the rules on the scope and limitations of patent protection for biotechnological inventions for the EU is the Directive 98/44/EC of the European Parliament and of the Council of 06.07.1998 on the legal protection of biotechnological inventions, which has been implemented to Ukrainian legislation also (hereinafter — Directive 98/44/EC). For today, in Ukraine the patent protection for pharmacogenomics invention is guaranteed under the basis of such normative legal acts:

• the national legislation — the Civil code of Ukraine[12], Law “On the

*United Nations Universal Declaration of Human Rights 1948, ‘Article 27. 1. Everyone has the right freely to participate in the cultural life of the community, to 81 enjoy the arts and to share in scientific advancement and its benefits’ URL: http://www.jus.uio.no/lm/un.universal.declaration.of.human.rights.1948/portrait.a4.pdf.
Protection of Rights to Inventions and Utility Models” [6];
• the international level — Agreement on Trade-Related Aspects of Intellectual Property Rights [13];
• the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part [14];

Concluding remarks
As it was mentioned the knowledge of the human genome sequence has enabled the understanding how the genetic information determines the development, structure and function of the human body. Owing to recent advances in the deciphering of the human genome sequence, high throughput genotyping technology has led to the reduction of the overall costs of genetic testing and allowed the inclusion of genotype-related dosing recommendations into drug package inserts, hence enabling the integration of pharmacogenomics into clinical practice.

The advent of personalized medicine is moving us closer to more precise, predictable and powerful health care that is customized for the individual patient. What also provides to create the individual’s electronic health data which will be derived from analysis of biological material and behavioural data, that will give possibility for determining the best way for treating depending of the genotype belonging individual patient. But along with the incredibly positive effect that produces pharmacogenomics in the process of diagnosis and treatments for new and known diseases, taking into account individual patient characteristics to the perception of therapeutic agents and general therapy, in parallel, there is the threat of the use of such knowledge as a universal weapon for bioterrorism. So, the basic question arises in terms of providing an appropriate level of protection for databases that are the basis of the results of the pharmacogenomics research as the use of such information may provide training act of bioterrorism aimed at the extermination of a certain genotype of people, for example on racial identity.

In turn, as an instrument to ensure the protection of high-tech research results in genetic engineering is used traditionally institute patent law. Considering that the pharmacogenomics can provide the principles that help clinicians to develop strategies against diseases are relevant of biological weapons proliferation, patent protection for these results seems an important part for guaranteed investment to this technology area.

However, further research is required on the principles of providing patent protection of results of intellectual activity in the pharmacogenomics field as well as about the consequences of guaranteeing exclusive rights to such inventions, especially from the point of view of prevention and protection from bioterrorism.

Список використаних джерел / List of references
1. Konstantinos Mitropoulo, Golden Helix Institute of Biomedical Research, Athens, Greece, Lindsey Johnson, Charité Universitätsmedizin, Berlin School of Public Health, Berlin, Germany, Athanassios Vozikis, Department of Economics, University of Piraeus, Piraeus, Greece, George P. Patrinos, Department of Pharmacy, School of Health Sciences, University of Patras, Patras, Greece, Relevance of phar-


5. The Jackson Laboratory, What is personalized medicine?. URL: https://www.jax.org/genetics-and-healthcare/personalized-medicine/what-is-personalized-medicine#.


9. Jing Luo, Aaron S. Kesselheim. Evolution of insulin patents and market exclusivities in the USA, Program on Regulation, Therapeutics, and Law, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital, Harvard Medical School, Boston, MA 02120, USA


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Армаза-Армаза Э. Х., Пысева В. Обзор нового объекта патентного права, который соотносится с новым биологическим оружием и имеет отношение к фармакогеномике. В данной статье рассматриваются вопросы, связанные с новым современным объектом патентного права, который является результатом исследования фармакогеномики; определение роли патентной защиты для изобретения в сфере фармакогеномики в соответствии с законодательством Украины и сравнение их с критериями в соответствии с ЕС. Кроме того, в этой статье описывается проблема возможного появления персонализированного биотерроризма, который будет рассматриваться в зависимости от генотипа человека. В заключение рассматриваются основные правовые акты, которые в целом обеспечивают правила, касающиеся сферы применения и ограничений патентной защиты изобретений в области биотехнологии для Украины и ЕС.

Ключевые слова: фармакогеномика, биотерроризм, лекарственные средства, изобретения, интеллектуальная собственность, патенты

Armaza Armaza E. J., Pysieva V. General review of the new object of patent law which correlated to the new biological weapon and relating to pharmacogenomics. This article discusses the issues associated with the new modern object for patent law, which are the results of the study pharmacogenomics; the determination the role of the patent protection for pharmacogenomics invention accordance with the legislation of Ukraine and to compare them with the criteria according to EU. Also in this article described the problem of possible appearance personalized bioterrorism, which would considered depends on the genotype of the human. For the end article examines the main legal acts which in general provide the rules on the scope and limitations of patent protection for biotechnological inventions for Ukraine and EU.

Key words: pharmacogenomics, bioterrorism, medicines, inventions, intellectual property, patents