THE ISSUE OF PATENTABILITY FOR PHARMACOGENOMICS INVENTIONS ACCORDING TO UKRAINE AND EU LEGISLATIONS

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Abstract. This article discusses the issues associated with the new modern object for patent law, which are the results of the study pharmacogenomics according to Ukraine and EU legislations. 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 , the issue about the legal status of inventions in the field of pharmacogenomics and criteria of patentability for them becomes as one of the most important to solved on the beginning of pharmacogenomics era. The research results of the pharmacogenomics gradually assuming an important part in clinical practice in developed countries and becomes the main subject for research for pharmaceutical company. As a rule the world biggest's pharmaceutical companies' are interested to invest money to pharmacogenomic's research and involving such results to produce in the practice a "personification" drugs. 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. 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 in a one hand is the main instrument for protecting investments, and guaranteed earnings for pharmaceutical companies what provides the investments to new researchers. Although, on the other hand, patents in the pharmaceutical and pharmacogenomics areas rather becomes are legal instrument for manipulating 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 are. This article analyzes the patentability of inventions pharmacogenomic from the point of view of industrial property rights under the laws of Ukraine and the EU. In addition, this article aims to discuss the issues associated with the new modern object for patent law, which are the results of the study pharmacogenomics; the determination of criteria of patentability of pharmacogenomics in accordance with the legislation of Ukraine and to compare them with the criteria according to EU.

Key words: *intellectual property, patent, patentability, pharmacogenomics, personalized drug, genetics, bioethics.*

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 possibility 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, that 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 leaded to been granted a thousand of patent related to inventions based on genetic material. In turn, as an instrument to ensure the protection of high-tech research results in genetic engineering is used traditionally institute patent law. 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, 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 personalized medicine (aside from the benefits to patients), where is the benefit to the pharma industry? Given that research is expensive and the markets for personalized medicine are, by definition, smaller, - this is the main question the answer to which lies in the benefits of patent granted. The patent granted 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. Generally patents encourage companies to make the necessary investment for innovation, and provide the incentive for individuals and companies to devote resources to research and development. For example, drug companies would not be prepared to fund costly clinical trials without being able to claim exclusive rights to compounds which once developed can be easily copied. Moreover the patents promote innovation in a legal way through the patent law, according to which the applicant to fully disclose his invention in the patent application, which is published 18 months after filing. Patents thus provide access to information about the latest innovations, which adds enormously to society's knowledge base and advances science and technology by allowing others to "stand on the shoulders of giants". The disclosure theory argues that a patent guarantees the publication of the results and the deposit of the product, or modified organism, in a central repository, for use in the future development of research to create better inventions (Macer, 2002).

An alternative system for protecting an invention against being used by a competitor is keeping it as a trade secret (WIPO, 2018). The closing of results from other workers is against the principle of scientific openness, but is a common feature of certain forms of industrial research, especially when the process used to create product may be expected to be kept a secret for some years. But anyway in a case which biotechnology inventions, once the product is sold, the DNA can be sequenced and reproduced by another team of researchers. This because of specific techniques, such as nuclear transfer or cell manipulation techniques may be kept secret a little longer, but still tend to be made open through the patent system (Darry, 2009). However, this latter possibility is small, given the current state of molecular biological technology that easily allows protein, RNA and DNA sequencing.

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 pharmacogenomicsd 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"* (UN, 1949).

The principal benefit claimed for patents is that rewarding an inventor creates a positive and open environment for progress of research, which leads to the betterment of society (Resnik, 2001). But the historical review suggests that the financial interest in a free market creates more funding for research, especially this considering to genetic and pharmacogenomics research where faster overall progress in important areas has been the result of intense research efforts with financial benefits for investors.

However, in a case of pharmacogenomics invention there are suggested that patent protecting may even inhibiting researching by the discouraging investment into areas where already are many broad patents (Heller, 1998), and still have not have strictly 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 been became as a one of the more controversial aspects of biotechnology, which has not been a such required for early patenting on medical products of biotechnology, such as insulin (Luo, 2016), 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, which how has been mention earlier prognosed to create a personalised medicine and drugs, has captured the greatest public attention and controversy under the issue of patentability criteria.

Currently, research is moving forward in regard to gene therapy in pharmacogenomics is aimed at create the new methods for diagnosing diseases and individual drugs. Gene therapy consists in using nucleic acid as a therapeutic composition in medicine. The simplest method of use for gene therapy is to compensate for abnormal expression of a gene (Croyle, 2007).

In order to protect the result of pharmacogenomics research, legal regulations provide a system of protection based on the exclusive patent, which guarantees the inventor the rights of exclusivity over the biotechnological finding.

In general, a pharmacogenomics patents may consist in a composition of matter, a method for obtaining or utilizing one or more of these, or a product which combine such element. Contrarily, the hypothesis that a patent application may concern a naturally occurring biological substance in itself, regardless of whether it refers to a specific procedure or use associated with it, given that it has been sufficiently "isolated" from its natural state, is one of the most controversial points of the debate on the subject (Stazi, 2015, p. 6).

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 (Killey, 1992) individual mutations, expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).

Protection conferred by a patent relating to biological material having specific properties extends to any biological material derived from this biological material by reproduction or multiplication in an identical or variant form and possessing these same properties. Protection conferred by a patent relating to a process for the production of biological material having specific properties extends to biological material directly obtained by this process and to any other biological material obtained from the directly obtained biological material, by reproduction or multiplication in an identical or variant form and possessing these same properties (Knoppers, 1999).

Protection conferred by a patent to a product containing genetic information or consisting in genetic information extends to any material in which the product is incorporated and in which the genetic information is contained and fulfills its function, with the exception of plant and animal varieties.

The main legal act which provides the rules on the scope and limitations of patent protection for biotechnological inventions for EU is a Directive 98/44/EC on the legal protection of biotechnological inventions, which has been implemented to Ukrainian legislation also. For today, in Ukraine patent protection for pharmacogenomics invention are guaranteed under the basis of such normative legal acts:

- the national legislation - the Civil code of Ukraine (VVR, 2016), Law on the Protection of Rights to Inventions and Utility Models (Kravchuk, 2014) (hereinafter – the Ukrainian's Law on inventions);
- the international level - Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter - TRIPS Agreement), the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part (hereinafter – Association Agreement between the Ukraine and EU) (WTO, 1994);
- the standards of the European Union - Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter – Directive 98/44/EC), Convention on the Grant of European Patents of 5 October 1973, European Patent Convention (EPC).

In general the invention on pharmacogenomics has belonged to category of biotechnological inventions, as a biotechnological invention relate to products consisting of, or containing, biological material, or processes by means of which biological material is produced, processed or used. According to the Ukrainian legislation and to the mean European Union legislation the result of human intellectual activity in any field of technology is recognized as an invention only if the invention complies with the conditions of patentability. As mention on Article 8 Directive 98/44 for granted legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law, whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfill the requirements for patentability (EC, 1998).

General rule for the legal protection under Ukrainian's Law on inventions (Article 6), TRIPS Agreement (Article 27.2), European Patent Convention (Article 53(a)) and Directive 98/44 (Article 6) as a conditions of granting the legal protection for invention are prohibits granting patents to inventions whose commercial use would be contrary to "order public" or morality, and such use not being considered as contrary merely because it is prohibited by a law or regulation. Thus, the Ukrainian and EU law are pattern of providing minimal exclusions from patentability, shall be considered unpatentable:

a) processes for cloning human beings;
b) processes for modifying the germ line genetic identity of human beings;
c) uses of human embryos for industrial or commercial purposes;
d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes (EU, 2018).

However, we consider it appropriate to note, that is depending on the criteria of public order or morality is the most debatable for patentability criteria in general and in the field pharmacogenomics invention particular. As these are clearly indicated that is the criteria for further exploitation of an invention, rather than the nature of the invention per se, that is at issue with respect to assessment of the implications for "order public and morality". Like these categories are lies in the area of use the invention and not compliance with the conditions are, for example, any inventions of chemical and pharmaceutical industry can be classified as those which are contrary to public order, as may be used for the preparation and carrying out of an act of bioterrorism, or the letter bombs (letters enclosed with explosives) and antipersonnel mines. Of cause, these questions had been and continue to be as a one of the most hardest and required further study especially to innovative invention in biotechnology sphere. Anyway for now there are two general opinions on this issue, the so-called "American", which suggests that that morality should practically speaking have nothing to do with patents" (Schapira, 2000, 172 p.). And «European» that the grant of a patent is "ethically neutral" because it is logically and legally independent from actual commercialization of an innovation as well as from public policy decisions about particular uses (Crespi, 1995, p. 435). Thus the legal protection shall be granted to an invention (utility model) that does not contradict the public order, humanity and morality and complies with the requirements of patentability. The requirements for patentability inventions as under Ukrainian law as the legislation of EU are novelty involve an inventive step and are susceptible of industrial application.

A specific legal definition of novelty has developed over the years, with “novelty” meaning “made available to the public”. An invention (utility model) shall be considered to be new provided that it does not form part of the state of the art. Objects that are a part of the state of the art shall be considered only separately when determining the novelty of an invention (Kravchuk, 2012). In a fiels of pharmacogenomics that is means, that a human gene, which existed before but was “hidden” from the public in the sense of having no recognised existence, can be patented when it is isolated from its environment or when it is produced by means of a technical process and as long as its industrial application is disclosed in the patent application. The important for 'novelty' is that the substance is known, i.e. it must have been not only described, but also made available to the public. In Europe, a substance

is new in the absolute sense if there was no previously recognized existence which in practice means that the substance found in nature must be isolated from its surroundings (EC, 1998). Furthermore, the biological substance must also be definable by either its structure or by the process by which it is obtained to render it novel. The used process for the obtaining or the isolation of the novel substance can also be nove (Van De Graff, 1997, p. 164). For pharmacogenomics invention like biomarkers, criteria "novelty", the EPO (Wright, 2015) has reviewed its internal harmonisation notes and constant that claims in this area are now construed to implicitly include the selection (step) of patients as a limiting feature. For example, if a subgroup of patients to be treated is defined by allele X and the prior art does not disclose any test for that allele, the claim will be regarded as novel, even if the prior art discloses a large patient population which – albeit untested for – included patients with that allele. The policy also extends beyond alleles to patient groups characterized by expression profiles and methylation patterns. The inventive step or non-obviousness requirement is often a matter of much more discussion than the novelty requirement. In fact, while novelty can be recognized if no prior art discloses exactly the same subject matter of the claimed invention, i.e. all the same features, to access the inventive step is much more questionable. Generally, an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. The concepts to be taken into consideration are what is ‘obvious’ and who is the ‘skilled person in the art.

Obvious’ refers to an invention which is immediately evident, trivial or can be reached in a straightforward manner combining the teachings of the prior art. The person skilled in the art should be presumed to be a hypothetical person having ordinary skill in the art and being aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the “prior art,” in particular, the documents cited in the international search report, and to have had at his disposal the normal means and capacity for routine experimentation. The standard used by the EPO for the determination of inventive step is generally the problem-solution approach. Three-step test is used to determine whether there is non-obviousness. First the closest prior art and the technical effect achieved by the closest prior art is established. Then, starting from the closest prior art and technical problem, the claimed invention is considered whether or not it would have been obvious to the skilled person (Gerald, 2001). This last step is also known as “could-would” issue. The question is not whether the skilled man in the art could have found he solution to the problem with the aid of the prior art, but whether the prior art would have prompted the man skilled in the art to reach the solution as claimed in the invention. This is an objective assessment made on a predominantly technical basis which also taking part in Patent Examination in Ukraine.

The approach in the EU allows a known technique and protein sequence to bar patentability under the non-obviousness requirement. One of the earliest court decisions in Europe regarding non-obviousness as it applies to DNA molecules involved an invention directed to isolated DNA molecules encoding human tissue plasminogen activator (“t-PA”). In that case, oligonucleotide probing, the technique using in the claimed invention to produce human t-PA, was a known technique, and the skilled worker would have arrived at the claimed invention because the choice of oligonucleotide probes did not require skill and experience

of a high order. Hence the claimed invention failed for non-obviousness because the Court focused on the obviousness of the methods of isolating the DNA molecules. However, there may still be non-obviousness if there is evidence the isolation procedure was difficult. For example, when there were significant differences between the known marine and unknown human sequence of a gene, the isolation of the human sequence was non-obviousness because there was no reasonable expectation the marine sequence could be used to probe for the human sequence. In another case, the absence of suitable probes was another basis to find there was non-obvious for a DNA molecule (Gerald, 2001).

Although it is important to remember that discoveries (e.g. the mere discovery of natural substances, such as the sequence or partial sequence of a gene) are not patentable. However, if an inventor provides a description of the technical problem they are intended to solve and a technical teaching they move from being a discovery to being a patentable invention. The industrial application is a practically implicit requirement. In any case, it generally refers to the possibility to always reproduce the invention in an identical manner and to bring an advantage to the state of the art. In addition, a distinctive feature of the patentability of inventions in the pharmacogenomics field is their compliance with the criteria of utility, which is partly similar to the criterion of industrial applicability. Even if we accept that a DNA and ESTs are patentable, they may not be useful in the patent sense. As an example, the well-known patent for invention Myriad Genetics, Inc. relating to the BRCA1 and BRCA2 genes and associated genetic tests. These patent has allowing to diagnose breast cancer in its early stages, and to determine the presence of hereditary to development of breast and ovarian cancer in women. But because of high price for testing and also blocking the possibility of further research BRCA1 and BRCA2 genes the patent also puts into question the inventive criterion of utility for human society. Some examples on the field of biotechnology, patentable is – genes and nucleic acid molecules (e.g. disease-related genes for diagnosis or antisense, siRNA molecules for therapy) – proteins (e. g. insulin, erythropoietin for therapy, cellular receptors for drug screening) – enzymes (e. g. proteases for washing powder, cellulose degrading enzymes for the production of bio-fuels) – antibodies (e.g. for cancer treatment, pregnancy tests, or diagnostics) – viruses and virus sequences (e.g. hepatitis C virus and HIV for blood testing and the development of vaccines and therapies) – cells (e.g. hematopoietic stem cells for the treatment of leukemia) – micro-organisms (e.g. bacteria for bioremediation, yeast for food production) – plants (e.g. herbicide resistant soybean, “golden rice” which accumulates pro-vitamin A, drought-resistant plants and algae for capturing CO2 from the atmosphere) – animals (e.g. disease models for research such as the genetically modified “oncomouse”, donor animals for xenotransplantation, dairy animals which produce medicaments in milk). Instead in a biotechnology field are not patentable – sequences without a known function (e. g. expressed sequence tags (ESTs) resulting from automated sequencing) – genetically modified animals which suffer but are not associated with a substantial medical benefit (Khaleeli, 2018). Protectable inventions object in Pharmacogenomics area are products, composition and method.

The first category is products or tools which available to researchers involved in pharmacogenomics studies are viewed as patentable. These include reagents, kits, chips, microarrays, instrumentation; devices used for genetic tests, algorithms for searching and sequence alignments and database technology. Certain proteins may also fall under the tool category

if they can be used as probes to identify other biomolecules or small molecules. Next category is a composition. The composition of isolated nucleic acid sequence, isolated protein and small molecules can be claimed. A patent application has to comply with the requirements for utility, novelty and non-obviousness. Further, the patent application must also comply with requirements for written description, enablement and best mode. As the example, one has not shown utility if one claims a nucleic acid sequence that may be used as a gene probe, a primer in PCR, a chromosome marker or an antigen generator since such utility is applicable to virtually any nucleic acid sequence. However, if the function of the gene is known and its utility is understood then claiming the DNA, as a gene probe, would be valid. Further, if the gene function is known and the utility is accepted then a homologous DNA sequence would comply with the utility requirements and could be claimed. Even if a portion of this homologous genev was previously published as an expressed sequence tag (EST), the patenting of this homologous gene still complies with the novelty requirement. While a single nucleotide polymorphism or a nucleic acid sequence containing such a variation can not be claimed, if such a variation proved useful as a marker for a disease state or for drug metabolism, the composition could be claimed. The written description requirement is the greatest hurdle for patenting of composition in inventions. In an age when *"describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself"* (Warburg, 2013) one can be sure that the written description requirement is very strictly enforced . The last category is pharmacogenomics' methods. Patenting methods that aid in the acquisition of pharmacogenomics data such as screening and genotyping methods is standard practice. Further, methods used in the diagnosis and treatment of subjects based on pharmacogenomics knowledge are also patentable. Interestingly, methods for management of complex data from pharmacogenomics studies such as a method for integrating clinical, diagnostic, genomic and therapeutic data is patentable. Finally, methods for pharmacogenomics-based clinical trial design meet the criteria for patentability (Thums, 1996).

However, the EPC explicitly rules out the possibility of patenting methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or composition for use in any of these methods (Wright, 2015). The exclusion of such methods is based on ethical and public health considerations, i.e. medical or veterinary treatments should be free from restrain. Instead, under Ukrainian legislative still present opportunities to get patent for methods for the treatment or therapy and diagnostic methods practiced (Kravchuk, 2012). The patentability of methods of treatment has been rejected mainly due to public health concerns around not permitting doctors the direct use of these methods in their practice. The unpatentability of medical treatments helps preserve doctor's therapeutic freedom, and is at the heart of the civil, criminal, and professional regulations that give meaning to medical ethics (Hsiao, 2012)

It is believed that allowing patent protection of medical methods prohibits the open exchange of information and ideas, drives up the cost of health care, impairs the quality of care and human life, may be unnecessary and can be subject to abuse. Similarly, the American Medical Association and Council on Ethical and Judicial Affairs has also raised concerns about patenting medical procedures because of the restriction placed on academic

and clinical access to those methods, the increasing financial burdens and the difficulty of enforcing medical process patents when enforcement might compromise patient confidentiality (UIPI, 2018).

However, need to note that there are other thoughts that these concerns can apply equally to all medical products, processes, and diagnostic tools regularly used in clinical practice and fail to answer why medical methods are the exception.

As a possible rationale could be the fear that patents will prevent doctors in emergency situations from using the patented method if they don't hold the license to do so. But on this case the infringement would be justified regardless of whether doctors could obtain permission so that the proper treatment could be provided and the endangerment of patient lives could be avoided. Also need to noted that under Ukrainian patent law a product, process, or a new use of a known product or process in pharmacogenomics area can be patented as utility model. For example, such articles as pumps, seals, pharmaceutical compositions, methods of treatment of diseases and ways informing consumers may be patented as utility models. The number of utility model applications is twice as large as applications for inventions in Ukraine. Thus, to Ukrpatent for the 2017 year was filed 6 645 applications for utility models, while for inventions - only 2 896 .

The main differences of a utility model and invention are:

- ✓ A Criteria of patentability: In order to obtain a patent for a utility model, the solution should be new and industrially applicable. Among the other conditions, the invention should have an inventive step.
- ✓ Conducting an examination: An application on obtaining a patent to a utility model passes only a formal examination, where is cheked all filled documents and objects reffering to objects of technology. a patent for a utility model issued under the responsibility of the applicant as a technical solution is not verified in fact.
- ✓ Patents Duration: The term of validity of a utility model patent is 10 years from the date of filling an application, the patent for the invention - 20 years. n.
- ✓ The protection reliability: To dispute the patent for a utility model is much easier than an invention patent as the first have a declarative form. In order to obtain a patent for an invention a technical solution is examined on availability of novelty, an invention step and industrial applicability.

As we can see it is fairly easy and cost effective to get a patent for a utility model, whereas the application passes only formal examination in contrast with obtaining a patent for invention. In other words, the object which is claimed is not checked in fact - for compliance with the terms of legal protection - novelty and industrial applicability. So, if you prepare a properly application, description, claims, abstract, pay fees and observe other formal requirements, you can get a patent for utility model for an obvious object on any technology field. According to the Ukrainian Legislation, the expert of Patent Office has no grounds for refusal to grant such a patent, which leads to the question of abuse of intellectual property rights, and the use of utility models as instruments for unfair competition, as evidenced by the multiplicity of litigation, for example on the recognition of patents for utility model invalid due to lack of novelty. In addition it should be noted that the use of patent protection of utility models regimes in the fields of pharmaceuticals and pharmacogenomics creates an additional barrier in the accessibility of sciences research results. Currently, a small but sig-

nificant number of countries provide utility model protection. These include: Australia, Argentina, Armenia, Austria, Belarus, Belgium, Brazil, Bulgaria, China, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Guatemala, Hungary, Ireland, Italy, Japan, Kazakhstan, Kenya, Kyrgyzstan, Malaysia, Mexico, Netherlands, OAPI, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Slovakia, Spain, Tajikistan, Trinidad & Tobago, Turkey, Ukraine, Uruguay and Uzbekistan. It is necessary to emphasize that the Ukrainian law too broadly defines the objects of the utility model. That is why during the reformation process in Ukrainian patent law and intellectual property law in general have been discussing a question to exclude from the list of patentability object as in utility model regime of chemical and pharmaceutical methods, foodstuffs, biological material and methods of surgical, therapeutic and diagnostic treatment of human and animal. As the conclusion, the criteria for patentability pharmacogenomics invention in Ukraine, with harmonization Directive 98/44, are very clear about the patentability of human genes and other biotechnology inventions. Patentable inventions in New inventions involving an inventive step and susceptible of industrial application are patentable, even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. After citing the above patentability requirements and stating that an invention involving biological material is also patentable, the Directive then stipulates that biological material which is isolated from its natural environment or produced by means of a technical process may be the object of an invention, even if it existed previously in its natural stat. However, 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 behavioral data, that will give possibility for determining the best way for treating depending of the genotype belonging individual patient.

The legal protection shall be granted to an invention in pharmacogenomics by the same criteria as for any other invention. Thus, for granted the patents for pharmacogenomics invention, these inventions should not contradict the public order, humanity and morality and complies with the requirements of patentability. The requirements for patentability inventions as under Ukrainian law as the legislation of EU are novelty, involve an inventive step and are susceptible of industrial application. At the same time the criteria of public order or morality is the most debatable for patentability criteria in general and in the field pharmacogenomics invention particular. As these are clearly indicated that is the criteria for further exploitation of an invention, rather than the nature of the invention per se, that is at issue with respect to assessment of the implications for "order public and morality" and this questions needed further research. Considering that the pharmacogenomics can provide the principles that help clinicians develop strategies against all diseases, patent protection for these result seems as a important part for guaranteed investment to this technology area.

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