PRESSING QUESTIONS OF LEGAL MODE OF APPEAL OF INNOVATIVE PRODUCTS, WHICH CONTAINS GENETICALLY MODIFIED PRODUCTS

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Topic of the research is actual due to the fact that intellectual property items become main innovative production; every day they more and more fill market of goods and services. Innovative production, which contains genetically modified products, needs careful examination by state in the process of its turnover. Active development of legal regulation of intellectual property right and biosecurity right determines the necessity of analysis of legal regime of turnover of special innovative production, paying attention to the need of keeping the balance of private interests of patent holder and public interests of state in providing framework for security of state biosecurity system.

Theoretical basis of research is based on works of native and foreign scientists, for example works of E. Artemyev, A. Belyakov, M. Boguslavskiy, G. Bodenhausen, E. Gavrilov, A. Gornisevich, J. B. Griffiths, Tu. Kapitsa, S. Komisarenko, O. Korchagin, S. Landkof, V. Oreshkin, N. Rybalskiy, V. Eyasentsev, Yu. Svyadosts, N. Finkel, I. Heyfets, etc.

The aim of the article is to examine peculiarities of legal regime of turnover of innovative production, which contain genetically modified products, in national

reality with tracking of influence of norms of patent legislation of Ukraine and legislation on biosecurity on this turnover.

Distinctive condition of use of patent rights is norm of part 2 of article 28 of Law of Ukraine “On defence of rights on inventions and utility model”, which note that "Patent gives to its holder exclusive right to use, invention (utility model) at his discretion, if such use do not outrage rights of other patent holders." This norm is basis that protects private interests of patent holder.

Public interests can be presented more complex, but their character is clearly expressed, from this point of view they are considered as corresponding to private interests. Limitation of patent rights, which are provided by legislation, is the public interest due to which full-value or not full-value balance will be formed.

National legislation contains several categories of patent limitations: by term, by territory, by provided cases of free use and compulsory alienation of rights on inventions.

Above mentioned facts show that in spite of opportunity of use of patent rights with the purpose of protection of society interests patent holder's rights can be limited. But cases of such limitation have exceptional character, in other words there can be no analogy of right or law. Limitation can be carried out only in cases, clearly provided by legislation. Balance of private and public interests is preserved. In case of any changes in this balance each of party can apply for right protection.

The second group of limitation of use of patent holder’s rights is related directly to the character of item, which is protected by patent - of genetically modified product. Peculiarity of this product defines certain peculiarities of limitation of rights on it. Except general limitations of patent holder's rights specific additional conditions will be used. Existence of these specific conditions is connected to potential risks, which can be caused by use of genetically modified products. Though

today there are no documented uncertainty fact of harm of genetically modified products, society reached a conclusion on constant and careful control under these items.

One if the reasons, with the help of which it is possible to prevent or decrease negative consequences of carrying out of genetic and engineer activity, it is possible to prevent infringement of person's right (for example right on safe for life and health environment, on ecological information, etc.), is carefully organised and executed legal regulation of relations in the field of conditions related to GMO (genetically modified organisms). Legal provisions can be the factor, which, by arranging of public relations arising in connection to the development of genetic engineering and use of its achievements, on the one hand, does not limit (and in some cases stimulates) further development of this sector, on the other hand, helps to avoid or minimize potential negative for human and environmental consequences of genetically modified organisms [2, c. 4].

Despite the fact that Ukraine has ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity by the Law of Ukraine of September 12, 2002, № 152-IV, legislators also passed national legislative acts of the public-legal nature, which, however, have a great influence on the process of disposal of private intellectual property rights, which arise from a patent on a genetically modified product.

According to the fact that genetically modified product as a result of human intellectual activity in the field of genetic engineering can become partially or directly a food stuff, medicinal drug or other object, it is necessary to review it in terms of turnover.

In Law of Ukraine “On defence of rights on inventions and utility model” it is determined that “the term of effect of patent on invention, item of which is medicinal

drug, means of protection of animals, means of protection of plants, etc., the use of which requires permit of a competent body, may be extended on application of the patent holder for a period equal to the period between the date of filing and the date of receipt of such permit, but not more than for 5 years. Fee for filing of application should be paid [1]." As we can see from the above mentioned rules, the legislator distinguishes such terms as the receipt of a patent on invention and civil turnover of products that use the invention. With regard to medicines and means of protection of plants and animals, it indicates the need to obtain the appropriate permits that take a lot of time of validity of the patent.

From the above mentioned we can conclude that for a subject of rights on genetically modified product not only the process of acquiring such rights plays an important role, but also their use, which is already crossed with the norms on turnover of civil rights and consumer rights protection.

So, according to the criterion of the turnover objects of civil rights can be divided into three types: 1) objects of uncontrolled distribution; 2) objects of limited turnover; 3) objects withdrawn from turnover [3, p. 98].

Despite the fact that implementation of genetically modified products into civil turnover requires obtaining of the appropriate permits, according to the criterion of turnover they can be attributed to objects of limited turnover

Among the national legislation that defines the conditions of turnover of GMP (genetically modified products) today there are: the Law of Ukraine "On state biosecurity system in the case of developing, testing, transportation and use of genetically modified organisms" of May 31, 2007, Resolutions of Cabinet of Ministers of Ukraine "Some issues on approbation (testing) and registration of varieties of genetically modified organisms of agricultural plants" of July 23, 2009, № 808, "On approval of the Procedure for issue of a permit for the state approbation

(testing) of genetically modified organisms in open system", of April 2, 2009, № 308, "On approving the Procedure for issuing of a permit for import on customs territory of Ukraine of unregistered genetically modified organisms with purpose of scientific and research works or state approbation (testing)" of August 20, 2008, № 734 and "On approving the Procedure for issuing a permit for transit movement of not registered in Ukraine genetically modified organisms" of April 28, 2009 № 423.

Law of Ukraine "On state biosecurity system in the case of developing, testing, transportation and use of genetically modified organisms" provides such norms, which influence on use of intellectual property rights:

- genetic and engineering activity in closed-loop system is a subject to licensing that is carried out on the basis of risk estimation in dealing with GMO in closed-loop system (article 12);

- it is forbidden to release GMO into environment before their state registration. Before the state registration release of GMO into environment is possible only with the purpose of state approbation (testing). The state approbation (testing) of GMO in open system is carried out exclusively on the basis of a permit issued by the central body of executive authority on ecology and natural resources (article 13);

- production, which is registered in State registers of GMO are: varieties of agricultural plants and breeds of animals, created on the basis of GMO; means of protection of plants obtained with the use of GMO; GMO source of food as well as food products; cosmetics and medicines that contain GMO or were obtained with their use; GMO source of feed, and also feed supplements and veterinary preparations that contain GMO or were obtained with their use (article 14).

Article 15 of the Law clearly specifies that "industrial production and introduction of GMO and products manufactured with the use of GMO before their state registration is prohibited. It is also prohibited to import on the customs territory

of Ukraine of GMO and products manufactured with the use of GMO, before their state registration, except those that are meant for research purposes or state approbation (testing)" [4].

All of the above mentioned norms are the direct cases, which are determined in patent legislation as follows: "Prohibition by law of commercial use of particular object on other grounds (except as provided in exceptions to patentability and items, to which protection is not granted under the patent law) does not influence on applicability of the relevant invention (utility model) for acquiring of rights on it" [1]. In other words, above mentioned standards do not influence on acquiring of rights on genetically modified products, however, directly influence on the possibility of use (turnover) of such products.

For the development of the legal regulation of the problem of biosecurity and the protection of rights and legal interests of consumers on information about the components of products, placed on the market, Verkhovna Rada of Ukraine on 17.12.2009 passed Law "On amendments to laws of Ukraine on delivery of information about the presence in the production of genetically modified components", by which requirements to the manufacturers and sellers to provide reliable information about the presence in the products of genetically modified components was intensified. Law "On amendments to the Law "On safety and quality of food products" (related to informing of citizens about the presence in food of genetically modified organisms) was passed. In accordance with this document, all food products in turnover in Ukraine, are labelled in state language and contain in accessible manner information on the presence or absence in products of genetically modified organisms (GMO), that are shown on the label of the product by the inscription "GMO" or " without GMO" respectively.

The tasks of these laws are: protection of human health and the environment in genetic engineering activity and handling GMO; providing constitutional right of citizens on reliable information about the content in the production of GMO components and their safe use; creation of conditions for safe practical use of GMO in the economic purposes; determination of rights and liabilities of subjects of regulation in handling GMO and establishment of responsibility for violation of the law; protection of citizens in case of causing harm to their health as a result of GMO consumption; establishment of legal framework for international cooperation in the field of genetic engineering activity and handling GMO, etc.

The requirements of these laws are compulsory on the territory of Ukraine for private and legal entities, which carry out activity connected to the handling GMO.

Information about the handling GMO and their potential influence on human health and environment is open and widespread, and therefore cannot be considered as confidential and secret, unless it is defined as a confidential and secret by legislation of Ukraine [4].

As can be seen from the above mentioned, in Ukraine the passing and implementation of special legislation of Ukraine in the field of genetic and engineering activity with the purpose of protection of human, keeping of biological diversity, protection of environment is initiated; it is developed taking into account foreign experience, in particular in terms of organisation and functioning of the regulatory approval system, realisation of monitoring of GMO, risk estimation for environment and human of genetically modified organisms, labelling of products containing genetically modified components. But implementation on the legislative level of fundamental rules on turnover of GMP, unfortunately, has not led to the establishment of this system in practice.

In this sphere of public relations the EU legislation today is much better and systematic than national. Among European legislation can be named such legislative normative legal acts:

- EU Directive 2001/18/EC (2001) that defines legal norms, which regulate the deliberate release of genetically modified organisms (GMO) into environment. This Directive defines the procedure for the approval of individual GMO or products consisting of GMO or containing GMO, through sequential, step by step, estimating of risks to human health or environment before any product will be released into environment or will approach a market.

Estimation of level of environmental risk includes evaluation and identification of potential harmful effects from GMO. This can be direct or indirect effects, cumulative and long-term effects on health and environment, risks associated with the introduction of the gene products, in which potentially toxic or allergenic proteins are used, as well as those that may cause effects such as, for example, the creation of genes that are resistant to antibiotics. The overall risk is determined as follows: determination of genetic characteristics that could cause undesirable effects; identification of potential consequences of each effect; estimation of opportunities for growth of these consequences; estimation of level of risk for each of these characteristics; implementation of management strategies for risks control.

- The EU Regulation 258/97 (1997) on new products and new food ingredients determines that all GMO are new food products, which require permit for their marketing. In accordance with this regulation GMO should not “be dangerous for the consumer” or “mislead consumer”, or differ from the usual food “by worse taste and nutritive properties for consumer”. The applicant files the application to member-country with the information, which demonstrates that the food product fully satisfy requirements of current security standards. Member-country conducts a preliminary

examination of GMO and sends it to the Commission or other member-countries. Their competent authorities can "provide comments or well-pleaded prohibition against marketing of this product", including the comments or objections on product's presentation or labelling. If there were no objections country-member will inform the applicant that the product can be marketed. If the GMO is permitted to market use, such a decision will indicate the terms of use, purpose of the product and the specific requirements for the labelling.

Provided in a general manner norms of European law allow concluding rather cautious and balanced position of the European legislator about the use of the products of genetic engineering. Such a position we take up within the framework of the European integration processes, but the norms of the national public law on genetic engineering activity need to be improved. Development of Ukrainian legislation on biosecurity should be implemented under condition of compulsive harmonisation with the relevant requirements of the European law in this field, which was formed as a separate institute of environmental law of the EU.

Therefore, the characteristic features of the turnover of innovative products, which contain genetically modified products, allow considering theoretical keeping of balance of public and private interests in the process of use of such products. The need to obtain special licenses, permits and carrying out of state testing, though it makes an additional burden for patent holder, should not be considered by him as a violation of his personal rights, because only with the help of such limitation the balance of interests of all members of society can be achieved. Only standards on legal regulation of genetic engineering activity should be improved, since in practice the mechanism of formation of system of biosecurity in creation, testing, transportation and use of genetically modified organisms does not work.

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LEGAL REGULATION OF SCIENTIFIC-TECHNICAL AND INNOVATIVE ACTIVITY

АКТУАЛЬНІ ПИТАННЯ ПРАВОВОГО РЕЖИМУ ОБІГУ ІННОВАЦІЙНОЇ ПРОДУКЦІЇ, ЩО МІСТИТЬ ГЕНЕТИЧНО МОДИФІКОВАНІ ПРОДУКТИ

Москалюк Н. Б.

Стаття присвячена розгляду окремих актуальних питань обігу інноваційної продукції, що містить генетично модифіковані продукти, зважаючи на їх подвійний статус: як об'єкта інтелектуальної власності та об'єкта особливої дозвільної системи.

Ключові слова: інноваційна продукція, цивільний обіг, інтелектуальна власність, генетично модифікований продукт.

АКТУАЛЬНЫЕ ВОПРОСЫ ПРАВОВОГО РЕЖИМА ОБОРОТА ИННОВАЦИОННОЙ ПРОДУКЦИИ, КОТОРАЯ СОДЕРЖИТ ГЕНЕТИЧЕСКИ МОДИФИЦИРОВАННЫЕ ПРОДУКТЫ

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Статья посвящена рассмотрению отдельных актуальных вопросов обращения инновационной продукции, которая содержит генетически модифицированные продукты, ввиду их двойного статуса: как объекта интеллектуальной собственности и объекта особенной разрешительной системы.

Ключевые слова: инновационная продукция, гражданское обращение, интеллектуальная собственность, генетически модифицированный продукт.

PRESSING QUESTIONS OF LEGAL MODE OF APPEAL OF INNOVATIVE PRODUCTS, WHICH CONTAINS GENETICALLY MODIFIED PRODUCTS

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The article is devoted to the specific aspects of circulation of innovative products containing genetically modified foods, because of their dual status: as an intellectual property object and as an object of particular licensing system. The author stydied abovementioned specific aspects for the purposes of the national realias and of the influence of patent law and biosafety rules. Also the provisions of the Law on Protection of Rights to Inventions and Utility Models are studying in this article. Special attention is given to the concept and types of limitation of patent rights. The author

notices that the legal framework of relations in the GMO-sphere is the prime factor that prevent or reduce the adverse effects of the implementation of genetic engineering activities, or avoid violations of individual rights. Because of the fact that GMO-foods is deemed to be a result of human intellectual activity in the genetic engineering field, it examines from the standpoint of tradability. The author suggests that the genetically modified foods are limited in circulation due to the fact that the introduction into civil circulation GMO-foods must obtain a permit (license). Also, the author analyzes Ukrainian and European Union legislation concerning with genetically modified foods sphere. As a conclusion the author says that domestic legislation on the genetic engineering have developed, but EU legislation in this field is much more advanced.

Keywords: innovative products, civil appeal, intellectual property, genetically modified product.