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Kashyntseva O. The reforming of the pharmacy legislation: avoiding speculations

P. 5

The article concerns the issues of national reforming of pharmacy legislation, including the draft Law of Ukraine «On Medicines» on the point of the patients' rights and access to medicines. The article presents the position of Intellectual Property Research Institute of National Academy of Law Sciences of Ukraine as for the invalidity of the increasing of data exclusivity regime up to 11 years and patent link in the procedure of the registration of medicines.

We have to stress that there are no legal grounds for increasing data exclusivity regime than the existing five years, as it is defined in Article 9 of the current Law of Ukraine «On Medicines». According to Article 222 of the Agreement of Association between Ukraine, on the one hand, and the European Union and its Member States, on the other hand, the data exclusivity period determines in 5 years.

And also in accordance of Article 219 of the mentioned Agreement of Association the parties have recognized the importance of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health. We also have to stress that the Agreement on Trade-Related Aspects of Intellectual Property Rights does not contain any provisions on data exclusivity regime.

Why it is so important for Ukraine?

The pharmaceutical registration institutions usually considered the application for registration of generic medicines referring to the documentation (dossier), provided

by the original producer and it is sufficient and does not require generic companies to conduct additional clinical trials on humans in order to obtain the data from such clinical researches required for state registration of medicines. Repeated conducting clinical trials contrary to the World Medical Association adopted ethical principles to be followed in conducting research involving human subjects and to the Good Clinical Practice.

The position of Intellectual Property Research Institute of National Academy of Law Sciences of Ukraine concerning the date exclusivity regime is corresponded with the position of WHO and UNDP which is determined in theirs documents.

Keywords: medicines, data exclusivity, pharmacy, patients' rights, human rights

Ennan R. General grounds of legal regulation of intellectual and creative activity

P. 10

The article deals with the features, attributes, types and nature of intellectual and creative activity. The correlation and delineation of the concept of intellectual and creative activities as well as philosophical foundations of the concept of creativity is done. The concept, features, legal nature, essence and significance of rights to results of intellectual activity are analyzed. Issues concerning the legal regime of exclusive rights, the specifics of intellectual products are studied. The theories and concepts of understanding the essence and nature of rights to results of intellectual activity are highlighted. The differences between the right of property (proprietary rights) and rights to results of intellectual activity are defined. The characteristic of intellectual property right as a new independent comprehensive law is given, the subject and method of legal regulation of relations in the field of intellectual property is singled

out. The legal status of subjects of intellectual property rights and the legal regime of intellectual property rights are highlighted. The notion of the content of intellectual property rights is investigated. The attention is paid to the analysis of functions and principles of intellectual property rights. The specifics of intellectual and legal relations (legal intellectual property) are also investigated. The analysis of sources of intellectual property rights is made.

Key words: intellectual activities, creative activities, intellectual property rights, exclusive rights

Vahonieva T. The concept of intellectual property rights and its components

P. 24

In the article the main categories of intellectual property right were investigated, some terminological problems of the conceptual apparatus of intellectual property right were analyzed and separate inherent characteristics of the objects were determined.

Copyright and related rights and industrial property rights are the part of the intellectual property right which is the part of civil law. In the regulation of intellectual property relations, the general civil law principles, methods and other mechanisms of their legal regulation are applied, therefore intellectual property right can be considered a sub-branch of civil law, but with its own specific for this sphere of regulation of social relations subject. The main difference of the intellectual property right from the proprietary right is the peculiarities of their objects.

It was found out that intellectual property right in the subjective sense is identical to the proprietary right and lies in belonging to the owner of intellectual rights the possibility to own, use and dispose of the corresponding object. A characteristic feature of property right to the

objects of intellectual activity is the origin of these objects and exclusivity of the rights on them, which lies in the exclusive right of the subject to authorize the use of the object of intellectual property to other people; to prevent an unauthorized use of the object of intellectual property right, including prohibiting such use.

The necessity of distinguishing the concept of «intellectual property right» from the concept of «intellectual property» and «intellectual activity» was determined. During the study of the objects of intellectual property right the term «creative activity» is often used, because creativity is a prerequisite for the creation of the objects of intellectual property right and in most cases is one of the main criteria for the emergence of intellectual property right.

It was determined, that the majority of the objects of intellectual property right are created as a result of intellectual creative activity, however these concepts cannot be considered the same and creativity is an optional criterion of referring the result of human activity to the objects of intellectual property right. It is almost impossible to formalize all these criteria regarding the characteristics of certain objects of intellectual property right through law. Because of this objects with different degrees of originality and novelty are protected by the same legal ways and means.

The result of the research is the conclusion concerning the need for a clearer definition of the general features of all objects of intellectual property right, legal confirmation of their defining characteristics that will enable to refer this or that new intellectual product to the objects of intellectual property right. The content and structure of each institute of intellectual property right should include a system of rights that will reflect the peculiarities of possession, use and disposal by the appropriate people of the rights of the objects of intellectual property right.

Key words: intellectual property, intellectual activity, creativity, creative activity, intellectual rights

Kulinich O. Protection of the interests of a natural person in creation and use of the photographs and other artworks with his own image

P. 33

The features of safeguarding of the interests of a natural person in creation of certain types of artworks are described in the article. The classification according to the process of creating of works is carried out. The features of the works, the result of which depends on the ingenuity or the creative skills of the author, are determined. The features of the works, the creation of which affect mainly in the mechanical devices and the creative component is of secondary importance when capturing an image of an individual, are defined. The conclusion of the enhanced degree of protection of the interests of individuals while creating photographs and other works such like by the process of creating.

Keywords: image, the way of creation, work, a natural person, interest, protection

Taievska M. Actor of a theater as a subject of performance of theatrical art work

P. 40

The author examines the issues related to the definition of an actor of the theater as a subject of a theatrical performance of the work and analyzes the definition of an actor of the theater, as a creative person who is entitled to remuneration for their creative work and is the creator of the original performance of theatrical works (co-author of the director).

Changes in public perception of an actor of the theater led to the strengthening of its legal status as a subject of

Performance of theater. But unfortunately, the legislator clearly defined property rights to his performance as an object of related rights, which in practice leads to some controversial issues, including recognition of the actor on the right to receive fair remuneration for their performance and even recognition of the right to an actor authorship of such performance.

Determination of the special status of the dominant actor of theater is in the plane of the disclosure features of his work, which is directly linked to the special nature of the work of theatrical art, which is a performance that does not live in the centuries as a work of plastic art, and lives only in the moment of creation. While theatrical performance goes, a work of art live theater, the play is over – and has only abode of her memories, impressions. The work of theatrical art exists only at the moment of its creation and only at this moment is perceived by the audience. The objective form of expression of a work of theatrical art is a «live» game theater actors as display their work at the time of creation of the work during the performance.

But it is believed that the director was the master of the theater. Beside it reduced the value even former actor and the actor’s personality charm somehow receded into the background. The figure of the director, invisible on the stage, in fact, filled the entire theater building could be seen for each existing character.

This attitude displayed to the person of the director and the legislation of Ukraine. In practice, the actor is the only employee that the will and the director receives a fixed salary for it, without his creative contribution to the work of theater.

The legislator must implement the rules of the Rome Convention which was ratified by Ukraine and brought in line with a special law «On Copyright and Related Rights» regulations «On

theater and theatrical work» concerning property rights actor to clear their determination. So, as of today property rights are governed by theater actor employment agreement without regard to these rights. The proposed changes in the law should serve society formation in the perception of the actor as the creator of his performance, not a tool in the hands of the director.

Keywords: actor, a work of theatrical art, producer

Trotska V. Foundation of the institute of free use works during XVIII–XIX centuries: historical and legal aspects

P. 46

The article contemplates the questions of definition in laws of different countries regarding free use of works during XVIII–XIX centuries.

This period covers the time from enactment of the first legislation in the copyright area – The Anna's Statute (1710) and before enactment of the first international treaty – The Berne Convention for the Protection of Literary and Artistic Works (1886).

The article contemplates factors that contribute to appearance of the institute of free use of works. First of all, the appearance of copyright connected with economic factors such as interest in the distribution of literary works. As the case might be, publishers had some profit from the use of such works. The laws of different countries were defined first norms that determine the exclusive rights of publishers and authors.

However, the exclusive (monopoly) rights lead to aggravation of social relations in part the possibility of free public access to the information, knowledge and cultural heritage with educational, scientific and other purposes. These rights were absolute.

The way out of this situation is considered defining of some exceptions in the law, under which the use of work (or part of these works) by any person is possible without the permit of the author (his heirs).

In the nineteenth century the development of international relations needed a new approach to the legal regulation.

The application of the laws of separate countries was limited to its borders, so it was necessary to overcome the differences in legal regulation of relations.

The initiation of the international protection of copyright is relating to the adoption of the The Berne Convention for the Protection of Literary and Artistic Works (1886). Specific norms of free use of works are determined in this Convention.

In general, the article contemplates some cases of free use of works that were defined in the laws of different countries.

The author pays the special attention to consideration of the judicial precedents in this area.

In the end of the article author concludes the information.

The institute of free use of works overcame the long and difficult path of appearance. Internal and external factors influenced the appearance of this institute. The introduction of this institutive in the laws of different countries occurred much later than introduction of copyright protection to works.

Keywords: authors, publishers, exclusive rights, limitations of property rights, public and private interests, internal and external factors

Pyseva V. The requirement of biosafety for pharmaceuticals as objects of industrial property: the current state of legal regulation

The article concerns of biosafety requirements for pharmaceuticals and to the general criteria on the patentability of industrial property, in terms of balancing the private interests of the inventor and the public interest of community.

Under the Ukrainian legislation the term of biosafety understand like «state of the environment of human life in which there is no negative impact on its factors (biological, chemical, physical) the biological structure and function of the human person in the present and future generations, and there is no irreversible negative impact on biological object of natural environment (biosphere) and agricultural plants and animals».

In the field of pharmacy biological safety is the criterion that applies to biological and biotechnological origin drugs, i.e. products of genetic engineering.

Thus, the development of genetic engineering in the pharmaceutical industry, providing endless possibilities for scientists to develop new and improve existing drugs in constant evolution of humanity and the world of living organisms, viruses and other pathogens, imposes a duty to ensure maximum of biological safety of such products.

In turn, as an instrument to ensure the protection of high-tech research results in genetic engineering is used traditionally institute patent law, the object of which is genetically modified product as a result of human intellectual activity in the field of genetic engineering.

Patent law does not address the issue of biosafety as their ultimate purpose is intended to provide the legal protection of results of intellectual activity and ensure the development of science and technology with the use of the invention while not violating the rights of the inventor.

However, the requirement for biosafety could theoretically be included in the eligibility criteria for the invention of the principle of humanity, which we believe is particularly appropriate objects relative to the pharmaceutical industry that use genetically modified organisms as part of composition of medicines.

Simultaneously, it is advisable to note that according to the general principles of patent law, obtaining legal protection in the mode of the invention or utility model, not a precondition to the introduction of the object of economic turnover or any other commercial, non-commercial use.

The patent is not an authorization document to display a particular product on the market, that allows you to maintain a balance of private and public interests, including aspects of biosafety, as the patentee under Ukrainian law, if the product to which the patent issued in this case medicament comprising of GMO, for use on the Ukrainian market, this drug need to be register as usual drugs as well as make data about them to a special database products that contain GMO components.

That’s why we can tell that in Ukraine, pharmaceutical industry in the maximum level provided compliance with biosafety that is ensured by the system of legal permission, of use all product which include GMO organisms regardless of the presence or absence of patent protection on certain drug.

Key words: biosafety, industrial property, pharmaceuticals of biological and biotechnological origin, genetic engineering, the principle of humanity

The article deals with the concept, the essence of innovative business incubators of leading foreign and domestic economists. It reveals the main feature an innovative business incubator – support of small innovative business. Particular attention is paid to the activities of innovative business incubators.

Key-words: business incubators, innovations

Koval I. Payment of compensation for the illegal use of intellectual property object: legal nature and terms of application

P. 70

The norms of current legislation of Ukraine, that regulates payment of compensation (valid for one occasion money penalty) for the illegal use of intellectual property objects, are analyzed in the article.

The approaches folded in judicial practice of application of this method of protection of intellectual property rights are educed. On the basis of undertaken a study legal nature of indemnification as measures of responsibility of offender is certain. It is reasonable, that the terms of payment of compensation are unlawful conduct and guilt of offender. It is suggested to fix in the Civil Code of Ukraine provision stating that a one-time monetary penalty applies if the offender does not prove the absence of guilt.

Key words: protection of the rights, payment of compensation, intellectual property

Danyluk A. On the improvement of mechanisms for civil rights protection intellectual property

P. 79

The essence of intellectual property protection in civil law aspects is considered in the article. The place of the

protection of intellectual property rights in the national intellectual property system as a whole is determined. The influence of proper protection of rights at the development of national economy to creation of workplaces etc. is emphasized. It is emphasized that effective use and disposition of intellectual property rights is possible only at the creation of effective mechanisms to protect these rights. The examples of inception of ideology in international acts that govern sphere of intellectual property are shown. There are also examples of the recognition of the thesis in analysis of a condition of the national system of intellectual property and development of public policy in the implementation of the strategic objectives of the sphere. Also it is analyzed the national law and the theory of intellectual property rights in the part of singling of qualities, features and components of protection of intellectual property rights in civil law aspect. In particular, emphasizes that at objects of intellectual property rights (subject to certain exceptions) spreading methods of protecting the rights provided for in the Article 16 of the Civil Code of Ukraine. Also the author investigates ways to use alternative remedies for intellectual property rights. Particularly, it is concluded that although the dispute in the area of intellectual property can be resolved through of the trial, parties increasingly render their dispute to mediation under, arbitration and other alternative dispute resolution procedures. In particular, it is concluded that although the dispute in the area of intellectual property can be resolved through the trial, sides more often put forward their dispute within the framework to mediation, arbitration and other alternative procedures of dispute resolution. Thus, alternative procedures alongside patent legal procedure are the prospect the development of Ukraine in sphere of improving of the protection of intellectual property rights. Also the conclusion is made about the necessity of improvement of norms of the Civil Code of Ukraine in terms of possibilities of application of measures of civil protection.

Key words: intellectual property rights protection, civil protecting of intellectual property rights, alternative dispute resolution

Humeha O. The experience of the European countries in the process of improving of civil protection of intellectual property rights

P. 87

In the article the experience of certain European countries in the process of improvment of the protection of intellectual property rights, particularly in civil aspect. The role of globalization in world process of innovation development for which intellectual property is an integral part is determined. The role of WIPO and its organs in the improving of national systems of legal protection and protection of intellectual property rights is emphasized. The activities of Consultative Committee on protection of rights WIPO principles of his organization and tasks are analyzed. The custody on the part WIPO issues such as strengthen the capacity and granting support for the advanced training of at national, regional and international levels, and in the interests of national agencies and officials who possessing experience protecting intellectual property rights is emphasized. The expediency of national presentations of modes protecting intellectual property rights is proved.

As examples modern experience of Spain and Denmark in the process of finding the ways of improvement of organization, mechanisms and procedures protecting intellectual property rights is adduced. Particularly, the author analyzes the Spanish experience, which has become a pioneer in creating the coordinated institutional systems of combating with counterfeit products as at the national level and well as at the level of the European Union. The experience of Spain in the development of national bodies qualified to deal with intellectual property rights violations is investigated. In

particular, the activities of the Intersectoral Commission on combating violations of industrial property rights. In addition, it is focused on the issue of establishing a European observation point of intellectual property rights violations. Also the author analyzes the experience of Denmark, looking for new tools and capabilities for improving the protection of intellectual property rights, including civil law direction. Fundamentals and perspectives of creation in Denmark the special Group on protection of rights on the basis of the national Office of Patents and Trademarks is investigating. Also it is analyzed the activity of Ministerial network to combat infringements of intellectual property rights, created and acting in Denmark. The specified analysis is aimed at finding ways to use foreign expertise to build a national system of intellectual property protection based on European standards and principles.

Key words: globalization, protection of intellectual property rights, the Advisory Committee on protection of rights WIPO, the European observation points behind violations of intellectual property rights

Kadyetova O. The experience of the Republic of Moldova in building of the national system of legal protection and defense of intellectual property rights and the ways of its application in Ukraine (civil aspects)

P. 96

The article analyzes the experience of the Republic of Moldova in building of a national system of legal protection and defense of intellectual property rights in order to use its positive consequences for Ukraine. Usefulness of studying of experience of Moldova for building of the national system of legal protection and defense of intellectual property rights is substantiated. An emphasis is placed on the need for such elements as political freedom, the legislative framework, vital institutions and culture based on intellectual property,

the existence and development of society oriented on intellectual property. It is emphasized that to detect the true value of intellectual property must also be the professional, institutional, legal environment etc.

Experience of Moldova is studied both through the prism of national legislation and some institutional elements working in the system of coordination of their efforts to achieve the defense of intellectual property rights. It is proved the usefulness of the adoption in Ukraine of the National Strategy in the field of intellectual property. For this aim the experience of Moldova, in which when forming similar strategy activity focused on basic purposes is analyzed. The author analyzed the achievement of such goals, including: forming a balanced legislation in the field of intellectual property; strengthening the institutional framework of intellectual property and conducting information-education campaigns among the public. The position of special legislation in a field of intellectual property including in part of defense of intellectual property is analyzed. Attention was addressed to the practice of application of law in the process of providing of defense of intellectual property rights, including various legal aspects such defense. National policy orientations in this area are determined. As an example of successful coordination of joint efforts of the authorities, rights holders and the public the activities of the Supervisory Committee over compliance of rights of intellectual property, that is working in Moldova are given. Conclusions are done about the ways of using the experience of Republic of Moldova in Ukraine.

Key words: intellectual property, defense of intellectual property rights, a national strategy in the field of intellectual property

Orlyuk O. International educational program «Idea, utility invention, innovation and intellectual property – Seed Project 2015» and its results for Ukraine

The article analyzes the results of participation of Ukrainian delegations in the International educational program «Idea, utility invention, innovation and intellectual property – Seed Project 2015», which was held in October 2015 in Seoul (South Korea) under the aegis of WIPO, the World Women Inventors and Entrepreneurs Association, WWIEA and the Korean International Cooperation Agency, KOICA. It is emphasized that the goal of the Seed Project is an opportunity to deepen knowledge in the process of creativity, invention, innovation, protection of inventions and managing intellectual property rights. The aim of Seed Project is rendering opportunities to deepen knowledge in matters of the creative process, inventive act, innovations, protection of inventions and intellectual property rights management. The role of WIPO in the development of innovations and IP systems in countries with a transitional period is emphasized.

The author analyzes the state policy of the Republic of Korea on the course of development of creativity, inventiveness, creative, especially as a paradigm in Korea is identified the transition to Economies of creativity. It is emphasized the economic, social and scientific achievements of political model of Korea, which through economic activity relies on scientific knowledge, creativity and taking initiative, resulting in created new driving forces of success, a new market and new jobs. Specific steps that are being realized both at government programs and at the level of companies are analyzed. The activities of governmental institutions in sphere innovative development of Korea are investigated. The WWIEA experience in the part of leading the policy development of women's resources on the basis of creativeness is described. The article emphasizes the importance of teaching methods used in the system of national policy. There were given the examples of teaching the creative thinking in Korea and methods of teaching, techniques of thinking, programs of

development creativity and teaching STEAM, development of action plans, practice solving creative problem etc. The qualities that have to be in people from developed countries in the future, among which distinguish the ability to solve problems through creative approach, critical thinking, ability to process the information, the ability to communicate are singled out. The conclusions about the prospects of introducing the Korean experience in Ukraine are being made.

Key words: utility invention, innovation, intellectual property, Seed Project 2015, Republic of Korea, Ukraine

Kashkanova N. Legal Aspects of determination of the criteria for the classification of the biomedical researches

P. 114

The article concerns the legal aspects of determination of the legal classification of the medical and biological researches. In particular, the author analyzes the existing evidence-based approaches of scientists who examined all relevant aspects of the medical-biological experiments on human beings and other medical research. Separately, the author determines the nature of the various criteria of classification of biomedical research.

The scientific validity of knowledge about the variety of medical-biological experiment on the human beings proves the complexity and the multi-nature and essence of the modern law doctrine and the practice legal phenomenon. However, analyzing the types of the medical-biological experiment is a complex scientific process that involves finding and isolating certain phenomenon specific to the legal classification criteria according to which it is necessary to analyze the kinds of medical-biological experiment on the humans. This separation provides varieties of the phenomenon specifying characteristics (information) about its content and the essence.

Implementation of the general classification to the essential functionality of biomedical researches presumes the implementation of different objects, phenomenon or even the process for the certain common characteristics.

The role of the classification has an influence to the feasibility of research on the basis of the unity of the object of such research and to determination of their essential patterns and other characteristics. It is particularly significant for the scientific validity to determine further trends of the researches design. The nature of the functional classification is relevant for the design of the medical – biological experiments.

The ambiguity and the multidimensional of biomedical researches is not framed only by the universal classification criteria. That is because its applying is not able to the fully reflect the objective characteristics of the essential features and the display of the biomedical researches on the human beings. So it seems possible to describe different classification criteria separately. However, the achievement of the specification is only possible basing on the scientific approaches of our colleagues who examined all relevant aspects of the biomedical researches on the human beings and other relevant medical researches.

The author concludes that the resulting scientific knowledge about the variety of biomedical researches on human beings prove the complexity, multi-nature and essence of the modern science into the law and the practice legal phenomenon. This determination provides varieties of the phenomenon specifying characteristics about its content and essence (design of the research).

Proper exercising and organizing of biomedical researches guarantee the relevant quality and new knowledge that will lead to their further implementation in the medical practice and the safe and effective impact on the human body for it’s

proper preservation, restoration and recovery.

Keywords: medical-biomedical research, medical and biological types of the experiments, clinical trials, pharmaceuticals researches, classification criteria, the domestic legal doctrine of biomedical researches