PROTECTING THE RIGHTS OF PRODUCERS ORIGINAL MEDICINES

OCHRONA PRAW PRODUCENTÓW LEKÓW ORYGINALNYCH

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ABSTRACT

Introduction: the article analyzes the state of protection of intellectual property rights of original medicine producers, its accordance with international standards. Attention is focused on the importance of exclusivity of medicine market.

Aim: the analysis of protection of intellectual property rights of medicine producers in Ukraine and determination of its conformity or non-conformity to the international standards.

Material and methods: the experience of certain countries is analyzed in the research. Additionally, we used statistical data of international organizations, conclusions of experts.

Results: there are numerous cases of state registration of generic medicinal products using the registration information of original medicinal products and delict of the rights of patent holders.

Conclusions: an effective mechanism of judicial protection of the original medicine producers` intellectual property rights from disorders that affect the profit was elaborated in Ukraine.

KEY WORDS: data exclusivity, original medicine producers.

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INTRODUCTION

It is known, the pharmaceutical market is the most competitive. According to it, is no surprise of plenty of judicial conflicts arising from rights violations of the pharmaceutical companies in the intellectual property field.

The intellectual property protection system functioning has no sense in any country if the right-holder is not able to maintains that belongs to him. Rights to intellectual property objects are worthless if no effectual system that ensures their effective protection [1].

Intellectual property right is a powerful tool which protects the investment, time and money and efforts that have been invested by the creator of idea or product. It gives the exclusive right to the creator for a certain period to the full use of his invention [2, p. 674].

Especially it concerns to the protection of the exclusive rights of medicine producers. Nevertheless, development and full clinical trials of new medical tool cost on average 1 billion dollars [3] and a full cycle of drugs manufacturing and bringing them to market is about 7-14 years. This process consists of the search and the development of molecules (1-6 years), preclinical disease research in vitro \ in vivo (5-7 years) clinical trials (6 months-2 years) and further monitoring.

Thereby, the new medicine production is expensive and long-term process however it eventually brings the profit of 200-300% [4] from the amount of opening costs to multinational and national companies (corporations).

According to it, analysis of risks of the bringing of innovation product (medicine) to the market is a strategic direction of activity of each pharmaceutical company. An analysis of judicial practice of the country which planes to bring this product to market has to become an element of this activity.

AIM

The judicial procedure of the intellectual property rights protection in the field of pharmaceutics is not the same and can often surprise with atypical solutions. It applies primarily to Ukraine and CIS countries. Therefore, the analysis of judicial practice in terms of the completeness of the protection of intellectual property rights of medicine producers in Ukraine is the purpose of our research. In addition to it, we focus our attention to the major issues of judicial protection of intellectual property rights of medicines manufacturers.

MATERIAL AND METHODS

The experience of certain countries has been analyzed in the research. Especially we analyzed the experience of the United States, India, EU countries. Additionally, we used statistic data of international organizations, conclusions of scientists and the regulations of international acts, which set the standards, and the principles of the protection of intellectual property rights of medicine manufacturers.

The main agreement in the field of intellectual property is The Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement) [5]. It has es-

tablished a unitary standards of the intellectual property protection. It reassured transnational pharmaceutical companies, which were worried about states with pharmaceutical industry which consisted of generic medicines (India for example).

It should be noted the Paris Convention for the Protection of Industrial Property [6], the Patent Cooperation Treaty [7] and the Directive of European Parliament and of the Council of the EU **No. 2001/83/EU [8].**

The theoretical bases of our research are the following researches: Pashkov V. [9], Olefir A. [10], Harkusha A. [11], Gutorova N. [12] and other.

RESULTS

Intellectual property is divided into two categories: 1) industrial property, which includes inventions (patents), trademarks, industrial samples and geographical indications of sources; 2) copyright, which includes literary and artistic works [2, p. 674].

The objects of copyright of pharmaceutical sector are reports of research and development works aimed at finding of original medicine, works of preclinical and clinical exploring of the medicinal product, development of methods for analyzing the substances and finished medicines, drafts of medical instructions for use. Inventions are divided into five categories: a) material or substance, auxiliary substance; b) pharmaceutical composition or the invention of the medicine; c) the way of substance obtaining; d) the way of using (treatment) of substances, which are already known as a medicine; e) the application of a substance known as remedy for a new purpose. Useful models include the equipment for manufacture of medical products. Commercial designation includes brand name of medications and company name or logo. [1].

There are three key elements for the functioning of an effective system of intellectual property: 1) it should provide fair and effective incentives to the innovations; 2) it should provide the certainty of innovators` rights; 3) it should ensure the means of coercion for protection of infringed rights arising from patents for the patent owners. Competitors can just copy the biopharmaceutical innovation without intellectual property rights as soon as they are safe and effective. Competitors offer their own version without spending time and money to development of medicines. Thus, innovators of biopharmaceutical industry may lose the ability to recoup their substantial investment to the development of new medicines [2, p. 674]. The analysis of judicial practice helps to provide an answer to the question of certainty of the innovators` rights and how these rights are protected.

We must note that patent are the most visible and perhaps the most important form of intellectual property protection and therefore profit protection. However, there are other tools which play a significant role. On the pharmaceutical market these tools include copyright, the protection of the exclusivity of clinical research, protection of the trademark [13].

The patent provide an exceptional level of control and ownership over inventions to the creators. It allows to the inventor to forbid other persons to use the ideas or inventions for commercial purposes without the creator`s permission for the time when a patent exists [14].

The desire for exclusivity market [14] is the engine that runs the patent legislation and judicial practice. The market of the exclusivity is a period, usually 20 years, when the company uses economic monopoly to its invention. These two decades of market exclusivity can bestow immense economic benefits for any inventor, and they have extremely importance for the success of pharmaceutical companies [15].

In accordance with article 39 the countries which have ratified the TRIPS agreement must protect the data clinical trials from an unscrupulous commercial use [5].

Data exclusivity of clinical studies - is the exclusive right of the manufacturer of the original of the medicinal product for a certain period to use your in own research summarized in the registration dossier on the own medicinal product in business purposes, primarily to bringing of the medicinal product to the market [16]. It provides a form of market exclusivity that goes beyond the granted patent rights [17, p. 187.]

So, in addition to the 20 years of action of property rights of the patent on the medicines, there is a "data exclusivity," which is determined from the date of first marketing licensing. "Exclusivity" compensates for the company-developer the enormous costs of clinical trials of the original medicines, while the generic companies to perform only a study on bioequivalence [16].

Modes of exclusivity are different in different countries. For example, in the United States for new medicines it is 5 years; for the medicines from orphan diseases - 7 years; for children's medicines is 6 months; for generics -180 days from the end of term of patent protection.

There are following modes of exclusivity in the EU: for centralized registration procedure – 10 years; minimum six-year period for all other drugs; for medicines from orphan diseases — 12 years; for children's medicines — 6 months [18].

The term of the exclusivity clinical research is 5 years from the date of registration without any exceptions in Ukraine.

DISCUSSION

We turn to the analyses of judicial practice when had proved the importance of the protecting of intellectual property rights of the producers of original medicines. We will focus on the most important points that are critical in building defense tactics.

The cases of protection of intellectual property rights of the original medicine producers are under the jurisdiction of administrative and economic courts depending on the defendant, the subject of the dispute etc.

Thus, the patent rights are protected in the order of economic proceedings. The cases concerning illegal state registration of generic medicines considered in administrative proceedings. The plaintiffs are holders of registration certificates or the holders of the patent in this case, and the defendants are The

State expert center of Ministry of health of Ukraine, or The Ministry of health of Ukraine. The offenders (the producers of generic medicines) are third parties in the case.

If the violation of these rights of the original medicine producers occurred, there are following ways to protect them: 1) to annul the order of Ministry of the health of Ukraine about the registration of medicines; 2) to admit illegal and annul the order of Ministry of health of Ukraine on registration of medicines; 3) to oblige the Ministry of health of Ukraine to make changes to registry of medicines (exclude the medicines from the State Register of medicinal products); 4) to oblige the Ministry of health of Ukraine to annul a registration certificate; 5) to recognize the valid registration certificate; 6) to recognize the illegal actions of State expert centre of the Ministry of health to provide positive conclusions and recommendations of the medicine to state registration; 7) to recognize invalid conclusions about the recommendation for registration medicines of The State expert center of Ministry of health of Ukraine (through unproven failure to prove indications for use); 8) to ban the medicines in civilian circulation on the territory of Ukraine; 9) to exclude the medicines from civil circulation on the territory of Ukraine.

To establish the presence or absence of infringement courts examine the circumstances which are proved and evidence. The circumstances that must be established are: 1) the fact of using registration information of the original medicine or the object of intellectual property (for example, applying the generics, the presence or absence of materials research, pre-clinical or clinical trials; the presence or absence of materials research, pre-clinical or clinical trials; the presence or the absence of the report regarding the bioequivalence or of questionable report on bioequivalence) by the defendant; 2) the fact of the violation of the registration information or intellectual property usage (the presence or the absence of the consent of the owner of the registration information of the patee); 3) the assessment of the legality (rule of law) of the order, adopted by The Ministry of health of Ukraine on registration of a medicine; 4) the fact of the violation of the procedure of State registration of medicines (the legality of providing positive conclusions about the effectiveness, safety and quality of medical conclusion and the recommendations for the registration of medicine by The State expert center of Ministry of health of Ukraine).

These factual circumstances can be supported with the following evidence such as the registration certificates of the plaintiff to the original medicine, plaintiff's patent to the medicines which are registered in Ukraine, orders of the Ministry of health of Ukraine about the registration of medicines, conclusions and recommendations of State expert center of Ministry of health of Ukraine about the registration of competitors` medicines, the materials of the registration dossiers of the plaintiff`s original medicine, the registration dossier of competitors` generics etc.

CONCLUSIONS

1) There are numerous cases of the state registration of generic medicines using the registration information of the original medicines, the violation of the patentees` rights.
2) Judicial practice of the intellectual property protection of pharmaceutical manufacturers is formed in Ukraine.

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