International Experience of using Parallel Imports to Ensure the Accessibility of Drugs

O.O. Bakalinska, Yu. Y. Atamanova, O. P. Orliuk

Abstract: ***The issue of IP rights protection of goods transferred through customs borders, in particular, medicinal products, became topical with the development of international trade. That is why there are many discussions on the parallel import and use of the rights expiration concept in the framework of modern integration processes. The article defines and discloses the features of the use of parallel import measures in the markets of original medicines and generics in different countries of the world and ways of ensuring fair competition in the specified markets; it also analyzes measures to stop anti-competitive behavior. The author also proves that parallel importing issues have not been properly resolved yet. Typically, parallel import matters are considered in terms of counterfeit products or the use of unfair competition in international trade. The problem of parallel imports is important not only in relation to a trademark use, but also in relation to the use of other types of intellectual property, inventions, etc. The approach of legislators and judicial practice to the prohibition or permission of parallel imports depends on the following factors: the ratio of interests of consumers of goods and intellectual property holders; commitments made in accordance with international treaties, both in the field of free trade (creation of a single market) and in the field of protection of intellectual property rights.***

Keywords : medicinal products, generics, replaceability, patent protection, licensing, compensation, competition.

I. INTRODUCTION

Pharmaceutical industry is one of the most successful and most influential sectors of the world economy, related to the research, development, mass production, distribution of drugs, mainly intended for the prevention, improvement, and treatment of diseases. Today, pharmaceutical markets are the most promising and most dynamic markets in the world economy. In addition to the economic aspect, the issue of the development of the pharmaceutical industry of each country is also important for the people well-being, the protection of human rights, life and health, the provision of patients with the necessary medicines of appropriate quality [1, p. 5-7].

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II. MATERIALS AND METHODS

The purpose of the study is to analyze the legal approaches to the application of parallel imports in various countries of the world to ensure the availability of medicines for certain population categories. When studying the international experience in the use of parallel imports to ensure the availability of medicines, the following methods were used: comparative law and generalization (in the analysis of approaches to the functioning of the pharmaceutical market in different countries of the world); analysis and synthesis (in identifying approaches to preventing illicit growing imports and other violations of competition law).

III. RESULTS

The existence of such a phenomenon as parallel imports (or "gray imports" in those countries where it is forbidden) has its advantages and disadvantages. The advantages are as follows:

1. Parallel imports do not allow the market to be split among manufacturers and their distributors, and thus allows lowering the product price in this market.

2. Parallel imports compel the rights holder to monitor the quality of goods delivered to any market, and not only to developed countries, which is beneficial to the average consumer.

And we may admit the following disadvantages:

1. Parallel imports open up opportunities for unfair competition.

2. If a trademark is promoted in the country by a distributor, and not the right holder, then after the trademark has acquired a certain reputation among consumers, the third parties importing the goods into the country in the framework of parallel import get unwarranted advantages over distributors.

3. Parallel imports impose significant obligations on the rights owner to ensure the quality of the goods, which are not always adequate to the market returns [7].

IV. DISCUSSION

Study problematics

The global pharmaceutical market is a complex, multilevel phenomenon with a steadily high growth rate of production, sales and, accordingly, profitability indicators. These reasons are related to the specifics of medicinal products as goods, the demand for which grows regardless of economic and political factors.

There are two main groups of drugs in the pharmaceutical markets: the original drugs and generics. Creation of any original (innovation) drug is

quite long and expensive process. In most cases, the development of a new drug from the stage of study of a new molecule to the registration stage takes more than 10 years, and the price of creating such a drug costs millions of US dollars. Only competitive innovative drugs are able to go through the long way from creation of a new molecule to the introduction of the drug into the pharmaceutical market. The basis of future success in the pharmaceutical markets is the demand for the drug and only time can show how competitive it will be.

Generic is a medicinal product, which is the reproduction of the original drug with the expired period of the patent protection to active pharmaceutical ingredients. According to the existing requirements, no significant non-clinical and clinical studies (compared to original drugs) are required for generics to enter the market which significantly reduces their cost. In most cases, the pharmaceutical, biological and therapeutic equivalence of these drugs is proven to be a prerequisite for recognizing the identity of the generic and the original. Today, the main requirements for generics are compliance with the quality, efficacy and safety standards of the original medicines.

The issue of IP rights protection of goods transferred through customs borders, in particular, medicinal products, became topical with the development of international trade. That is why there are many discussions on the parallel import and use of the rights expiration concept in the framework of modern integration processes.

Core Material Description

Parallel imports are another potentially beneficial mechanism within the framework of the Trade-Related Aspects of Intellectual Property Rights [2] for expanding access to medicines in developing countries. Usually it is a question of import and resale of products patented in the importing country, and legally advertised and sold in the exporting country. That step may be made without coordination with a patent holder. This is usually done in cases where registered medicines are sold in a importing country at a higher price than in the exporting country. Potential savings in parallel imports of vital medicines, in particular, in Kenya which succeeded in purchasing some anti-retroviral medicine, could be of major importance for countries with limited resources [1, p. 26, 191; 3].

As a rule, before using parallel imports, countries should develop and adopt laws that directly allow that. After that, they are largely protected from possible legal sanctions in accordance with article 6 of the Trade-Related Aspects of Intellectual Property Rights [2], which explicitly stated that no provisions of this agreement can be used against a WTO member state for a parallel import permit carried out in accordance with local laws of the country.

Parallel trade is a mechanism ensuring lower prices in the European market. In the various national markets, the proportion of drugs coming through those channels ranges from 1.7% (Finland) to 16.5% (Denmark). Parallel trade is allowed and encouraged by the European Commission as a tool for maintaining competition and reducing prices in the EU. However, the cost of such distribution is that the consumer prices of these drugs are ultimately not much lower than usual, that is, much of the value added is redistributed in favor of the intermediaries [4].

In its resolutions, the European Commission notes that parallel imports are predominantly cheaper than equivalent products; They play an extremely important role in providing the market with medicines at lower prices during patent protection, when generic is not able to enter the market.

Many developed countries, such as Sweden, Germany, Norway, Denmark, the Netherlands, the United Kingdom, use a variety of mechanisms and incentives to support parallel trade. For example, in Sweden, Denmark and Norway, drug interchangeability at the pharmacy level applies not only to generics but also to parallel imported drugs. In the United Kingdom, the reimbursement paid by pharmacies is reduced if their sales of parallel imported medicines are lower than the corresponding rate. In particular, in Sweden, prices for parallel imported drugs are 10 to 15% lower than the prices for the respective medicines [5, 6]. In several countries, parallel imports are definitely allowed, in some countries it is definitely prohibited, and in some countries its permission or prohibition is dependent on a number of factors, for example, the possibility of misleading consumers regarding the quality of goods.

Parallel imports supporting countries justify it as follows:

– interests of consumers, who do not care who makes the product if the quality of the product remains at the same level (Japan and Canada);

– the need in the national market support (Third World countries).

The permission for parallel imports corresponds to the interests of consumers, because it does not allow the right holder to set monopoly high prices for products and compels the right holder to honestly indicate the country of origin. For example, parallel imports in Japan are allowed, since consumer do not care where the goods are made, if they are responsible for the quality of the goods sold by trademark holders in Japan [1, p. 195; 6]. Those provisions were further established by regulations.

Parallel imports are closely linked to the concept of "expiration of rights to intellectual property". The possibility of a legal justification of parallel imports came with the development of the concept of international (universal) expiration of intellectual property rights, which is used for the following purposes:

– restriction of monopolistic activity;

– preventing the market from splitting;

– ensuring free circulation at the market.

In accordance with the basic principles of intellectual property law, the exclusive right exists for a specific product in which the protected intellectual property was used until the first introduction of that product into a civilian circulation. That is, if the product in which the protected intellectual property is used is entered into a civil circulation with the knowledge of the right holder, the exclusive right is considered to be "expired".

As the exclusive right to the intellectual property is territory-specific, i.e, it is valid only in the territory of the country covered by the respective protective document, it is the most logical to recognize its expiration in case of introduction of the product into circulation in the territory of the country covered by such protection. That is, the primary principle of "expiration of rights" was territorial and did not allow "to enter" the issue of parallel import into the framework of intellectual property rights.

Parallel imports may be prohibited or restricted by a state for the following reasons [7]:

– based on the interests of the right holders who incurred significant marketing costs for a particular trademark or technology, while 'gray importers", without spending money on advertising and implementation, can afford to set dumped prices for products (Spain, Russia);

– based on the interests of national security, since, in particular, medicines are of strategic importance to society, and, consequently, their quality should be greater than for all other products guaranteed by the trademark.

Special conditions of legal regulation of parallel import of medicines are established in different countries. In this case, it is necessary to take into account not only the intellectual property right, but also the administrative rules related to the regulation of the circulation of medicines in each particular country. However, when discussing the problems of parallel imports, law-making and law-enforcement authorities have to solve problems related to the import of medicines. As already discussed above, the Novartis judgment is based solely on the difference in the requirements for the documentation and the most medicinal product marketed in the US market. Similar restrictions are used in all developed countries: medicinal products are subject to registration; medicinal products must be accompanied by documentation of certain content; special packaging is required for medicinal products [8].

In the EU member states to ensure a unified economic space, not only the concept of "regional expiration of intellectual property rights" has been adopted, but also a system of import of medicines from one participating country to another has been developed. The doctrine of the "single source" was developed by the EU Court and to some extent similar to the above doctrine of "economic relation": products are deemed to originate from a "single source" if they are either made by two companies of the same group of persons or under licensing agreements with the exclusive right of the same person [9].

However, on April 1, 2004, in *Kohlpharma GmbH v. Bundesrepublik Deutschland*, the EU Court has ruled that medicines may be imported into the country under the "parallel import" procedure if the following conditions are met: they are lawfully introduced into the market in one of the EU countries, and are substantially similar to a local medicinal product. In particular, if the medicinal products contain the same active substance produced by the same manufacturer. Thus, by its ruling the court expanded the possibility of parallel imports, calling into question the doctrine of a "single source". That ruling has not been unequivocally judged by lawyers in the European Union, and further national court rulings do not follow such a treatment of parallel imports [10-12].

The United States is seriously considering the issue of allowing parallel imports of medicines only from countries with an effective regulatory system and recognized by the International Bank for Reconstruction and Development as a high-income country. Although, according to experts, such discrimination by countries in terms of income is in conflict with Article 4 of the Trade-Related Aspects of Intellectual Property Rights, "this is in the interests of social policy, and the possibility that this will lead to a dispute within the WTO is very small, since it is unlikely will appear a member of the WTO, which will have motives to initiate a dispute" [2]. Simplified procedure for registration of a medicinal product imported into the United States in the framework of parallel imports is also "taken up" in the United States.

Developing countries have their original approach to parallel imports. First, due to the social significance of drugs in poor countries, it is necessary that they be cheap and affordable, so in many countries the products are not protected as intellectual property.

The Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights, signed in 2001, made it possible for poor countries to postpone bringing their legislation in line with the requirements of the Trade-Related Aspects of Intellectual Property Rights, and, therefore, to ensure the protection of medicinal products as intellectual property before 2016. Secondly, in the poor countries, the institution of compulsory licensing is widely used for the use of technical solutions in medicinal products [13].

V. RESULTS

The above-mentioned measures allow the launch of cheap medicines on the market, and, with the permission of the right holder, that, in the case of permission for parallel imports from those countries, it can lead to a significant and unjustified reduction of prices for medicines in developed countries. Consequently, the restrictions imposed on the parallel import of medicinal products correspond not only to the interests of consumer safety but also to the interests of right holders.

In many countries, the rules related to parallel imports are established by international treaties: both in bilateral (the Free Trade Agreement between the United States and Australia, the Free Trade Agreement between the United States and Morocco) and in multilateral (the Trade-related Aspects of Intellectual Property Rights, the Rome Treaty on the EU) [14]. Moreover, in the case of international legal regulation from the countries, on the one hand, it is required to observe the balance of international obligations, the rules of free trade agreements and the single economic area, the most favored regime (with one side), and compliance with the requirement of protection intellectual property rights from the other side. In some cases, the rules governing parallel imports are established mainly through judicial practice (EU) or doctrine (Canada) [15].

One of the main ways to ensure the interests of right holders are the contractual regulation of issues related to the parallel import of goods. That is, the IP use contracts (licensing, agency, etc.), as well as manufacture and distribution contracts for goods in which certain intellectual property are used, may regulate the following issues: the territory on which the intellectual property of that person are used; the obligation of a person when entering a product to the market requires that such person's counterpart take all necessary measures to ensure that the product is distributed and used only in a certain territory; pricing policy; responsibility for preserving the quality of goods.

VI. DISCUSSION

In this case, the conditions relating to the restriction of the territory can be considered invalid, as they lead to artificial splitting of the market, and the conditions of the pricing policy may be considered as the use of

the dominant position in the market. According to American experts [15], in the EU such agreements can not be enforced because the European Commission promotes a policy of creating a common European market.

At the same time, the Free Trade Agreement between the United States and Australia, as well as the Free Trade Agreement between the United States and Singapore directly provide for the possibility of contractual regulation:

Article 17 (9) (4) of the Agreement between the USA and Australia: "Each Party shall ensure that the exclusive right of the patent holder to prevent the importation of a patented product or product made in a patented manner without the consent of the patent holder shall be limited to the sale or distribution of such product outside its territory, at least if the patent holder has imposed a restriction on such imports in accordance with agreement or other means."

Article 16 (7) (2) of the Agreement between the USA and Singapore: "Each Party shall ensure that the patent holder also has the right to transfer the rights to the patent and to conclude licensing agreements. Each Party shall provide for a claim at law to reject or correct the supply of a patented medicinal product without the consent of the patent holder by a party that knows or ought to have known that such a product is distributed in violation of an agreement between the patent holder and the licensee, regardless of whether the violation occurred in or outside the territory of such Party. Each Party shall ensure that, in the case of such a claim, the notification is evidence of constructive knowledge" [7].

VII. CONCLUSION

The approach of legislators and judicial practice to the prohibition or permission of parallel imports depends on the following factors: the ratio of interests of consumers of goods and intellectual property holders; commitments made in accordance with international treaties, both in the field of free trade (creation of a single market) and in the field of protection of intellectual property rights.

EU member states recognize the concept of regional expiration of intellectual property rights by allowing parallel imports within the European Union, with special conditions for parallel imports established for medicinal products. Right expiration may be national, regional or international. The international expiration of rights prevents the patent holder from further control over the product if it is already sold in any part of the world and thus contributes to parallel imports.

FINANCIAL DISCLOSURE

The concept of international expiration of intellectual property rights is the theoretical justification for the parallel import permit, and is recognized, in particular, in Japan, Canada and the UNA countries (the Unified Nations of the Andes, including Colombia, Venezuela, Ecuador, Peru and Bolivia). Parallel importing issues have not been properly resolved in Ukraine yet. Typically, parallel import matters are considered in terms of counterfeit products or the use of unfair competition in international trade. The problem of parallel imports is important not only in relation to a trademark use, but also in relation to the use of other types of intellectual property, inventions, etc. Moreover, the permit for parallel import of the latter has considerably less negative consequences for the right holder, because the improper quality of the goods used in the invention without the use of the trademark does not affect the business reputation of the patent holder in most cases. Thus, the issue of permitting the use of parallel imports to ensure the availability of medicines in Ukraine remains relevant and requires a great deal of professional discussion.

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It should be noted that each state must develop its own strategy aimed at ensuring the implementation of basic human rights, in particular, human rights to health, as well as ensuring the domestic market of the state of high quality goods corresponding to the purchasing power of people. And if, with regard to goods that are not vital, the question of the appropriateness of adopting the concept of international expiration of intellectual property rights may be controversial, this need is indisputable in relation to the goods that are needed daily to support the standard of living of citizens of the country. First of all, it's about medicinal products. The widespread strategy of originators is to create patent clusters by submitting a variety of applications that relate to the same product. For the same single drug, there may be dozens of valid and pending registrations of patents filed in different terms of the "life" of a medicinal product. In addition, the innovation company may "split" patent applications, and consideration of those "private" applications may continue, even when the general application is rejected or withdrawn, which is a source of uncertainty for generic companies.

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