Patent Protection of Pharmaceutical Products in the Globalising World Economy

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Abstract

Patenting new products in pharmaceuticals industry is of greater importance than in the other high technology branches of industry nowadays. Concentration of manufacturing takes place in pharmaceuticals industry as well as in the other branches of industry and it is characterised by the joining of firms. However, there are several specific features in patenting pharmaceutical products. Enforcement of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) made it compulsory to establish in all World Trade Organization (WTO) Members patent protection on pharmaceutical products and their manufacturing methods as well as patent protection of drugs. WTO Doha Declaration is an essential stage in patent protection of pharmaceutical products establishing the legal basis and compulsory licensing system. In 2005, the European Commission completed the Regulation of the European Parliament and the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

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1. Introduction

Nowadays patent protection of inventions is based on the national legislation of the states, the European Community legislation and several international treaties. Two international agreements - the Paris Convention for the Protection of Industrial Property
(the Paris Convention\(^1\)) with the amendments made later, dating back to 1883 (Paris Convention, 1994), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) dating back to 1994 - can be considered the original sources of the above-mentioned types of law. The TRIPS Agreement is actually Annex 1C of the Agreement Establishing the World Trade Organization (WTO\(^2\)) or the Marrakech Agreement (Uruguay Round Agreement: TRIPS, 1994).

The period before the Paris Convention can be characterised as a territorial period without international legal protection of inventions and the period since the Paris Convention (at least in Europe) as an international period. Then the global period of legal protection of inventions began with the TRIPS Agreement entering into force (Drahos, 2002).

The international period started in the 19th century, when the European countries concluded bilateral agreements on providing legal protection of industrial property with regard to application of national regime (Drahos, 2002). So, legal framework was prepared to be put into practice in the Paris Convention. The provisions of the Paris Convention can be divided into three main categories: application of national regime to nationals of foreign states, priority right on the basis of the first patent application and general principles a State party to the Paris Convention has to follow. These principles include e.g., independence of patents obtained for the same invention in different countries, the right to be mentioned as the inventor, restrictions concerning the grant of compulsory licences and several essential provisions belonging to the field of industrial property law (Summary of the Paris Convention, 2005).

The Paris Convention and the other international agreements and treaties administered by the World Intellectual Property Organization (WIPO\(^3\)) will enter into force with regard to the WIPO member state after the accession or ratification. During the accession to the treaty, a state can submit declarations and reservations not to apply or postpone the application of some provisions. The states try to use it as a means to achieve the balance between the sole rights of the proprietors of the intellectual property and the needs of the society according to the national law and the needs of the state and in this way regulate the development of economy in the state. For example, in patent protection during the period after World War II, many states took a chance not to protect particular kinds of inventions in order to develop a sector of their economy. One field where it was used was manufacturing of pharmaceutical products. Many states excluded patent protection of pharmaceutical products as a product enabling patent protection only to manufacturing technologies of pharmaceutical products.

The global period can be distinguished from the international period by the addition of „trade aspects“. It is natural to provide free and similar conditions for the movement of the capital and goods in the states participating in the global economy. The TRIPS Agreement fulfils this task, uniting the provisions concerning the global trade in the framework of the WTO and the basic provisions of the intellectual property law of the Paris Convention and the Berne Convention. Besides, the enforcement mechanism and the principles of application of the prescribed sanctions in case of the infringement of the rights are included in the TRIPS Agreement. A state cannot become

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2 Since 13 November 1999, Estonia is a member of the WTO.

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a WTO member unless it has acceded to the TRIPS Agreement and adapted its national law in the way that the state could follow without reservations all the so-called minimum standards of the legal protection of intellectual property established by the Agreement (Overview, 2005).

The main initiator of the TRIPS Agreement and its obligatory minimum standards of the legal protection of intellectual property was the USA, whose enterprises lost tens of billions of dollars every year, because of the inefficient legal protection of industrial property, especially on account of developing countries. The main aim of the TRIPS Agreement was actually to establish and enforce intellectual property rights in the developing countries, especially due to pirate and counterfeited goods exported from South-East-Asia and South-America (Ardagh, 2003, p. 2).

Concerning patent protection, the first and foremost requirement in comparison to the Paris Convention is that the member states have to enable without limitations to grant a patent to an invention of any field of technology, whether a product or a process, provided that it is new, involves an inventive step and is capable of industrial application. Besides, the grant of patent protection should not depend on whether products are locally produced or imported (TRIPS art 27.1). Proceeding from the viewpoint of a person (an inventor, the owner of a patent), inclusion of this provision in the international agreement is justified as it ensures equal rights to them despite the field of technology where the invention belongs to. On the one hand, this provision can be considered as a provision ensuring absolute right to property belonging to the field of human freedom basic of human rights (Drahos, 2002). On the other hand, this provision prevents the state from keeping the above-mentioned balance between the exclusive rights of the owners of a patent and the needs of the society by the national law. One field where the enforcement of the TRIPS Agreement has caused problems not only on the states level but also globally is patent protection of pharmaceutical products.

Actual problems of patent protection of pharmaceutical products due to the globalisation of the world economy will be analysed in the present article. The means designed by the European Union concerning the implementation of Chapter 6 of the Doha Declaration will be treated. Problems related to the availability and price policy of pharmaceutical products will be analysed from the point of view of Estonia as a new member of the European Union.

The results of a research carried out in the USA showed that nowadays patenting of new products in manufacturing of pharmaceutical products was even of greater importance than in other high technology branches of industry (Grabowski, 2002).

The high cost of working out new pharmaceutical products compared to the comparatively low cost of manufacturing their imitations has been brought out for the manufacturers of pharmaceutical products as the main reason for the importance of patenting. Safety requirements of the pharmaceutical products have increased the expenditures of the manufacturers of pharmaceutical products, which in turn have increased expenditures on testing in applying for the market authorization of pharmaceutical products. Besides, fees for the registration of medicinal products by the national drug authorities are constantly rising.

Therefore, firms manufacturing medicinal products and working out new products patent their products as a rule to compensate for their expenditures, obtaining a patent until the end of the validity of the patent and in many cases additionally an exclusive right for manufacturing and sales of the new medicinal products until the end of the validity of supplementary protection (Council Regulation (EEC) No 1768/92, p.1).
2. The Influence of Patent Protection of Pharmaceutical Products on Global Economy

The exclusive right based on patent protection is one of the essential factors in the process as a result of which nowadays manufacturing of pharmaceutical products is divided into two groups of manufacturers: the brand-name drug companies manufacturing new brand-name drugs and the generic companies manufacturing generic drugs after termination of the patent protection of the brand-name drugs or in the states where the brand-name drugs do not have patent protection, or old traditional drugs (Directive 2004/27/EC).

The price of generic drugs is usually 30-80% lower than that of brand-name drugs (Cox et al., 2005). According to the USA Generic Pharmaceutical Association (GPhA), the price of brand-name drugs was 96.01 dollars in the USA in 2004, whereas the price of generic drugs was only 28.74 dollars. This concerns prescription drugs. The percentage of generic drugs on the USA market is 53%, which is financially only 12% (GPhA, 2005). In comparison with the member states of the European Union, the percentage of generic drugs is approximately 41% in Germany, 39% in Sweden, 22-40% in Denmark, 22% in England and 12% in Holland. It is approximately 1% in Italy, Spain and Portugal and 34% in France (EU Policy Portal, 2005). So, brand-name drugs form a larger part of the drugs used in the industrially developed countries. High living standards of the industrially developed countries enable a greater impact of the brand-name drugs. Expenditures on drugs are estimated at 10-15 thousand euros per capita a year in these countries. This level of expenditure is not possible in the rest of the countries across the world, especially in the African countries, where the expenditures on drugs are less than 10 euros per capita.

At the establishment of the WTO people were convinced that the rearrangement of patent systems due to the TRIPS Agreement would be an impulse for a large-scale and fast transfer of technology from the industrially more developed countries to the less developed countries, including the so-called third world countries. However, at least in manufacturing and in relation to availability of essential drugs serious doubts have arisen (TWN, 2005):

- extension of patent protection of pharmaceutical products causes a rise of the price of pharmaceutical products, because the amount of the patented essential drugs is increasing which have special importance in the public healthcare;
- the gap in availability of pharmaceutical products between the developed and developing countries is still increasing. The key issue is whether the developing countries have to wait 20 years until end of the validity of the patent before being able to use innovative pharmaceutical products;
- WTO regulation (probably means the possibility to apply for compulsory licences solely to cover the needs of the local market) concerns only local manufacturing of pharmaceutical products, excluding the access of the poorer countries to the high quality generic drugs;
- it is unlikely that the TRIPS Agreement would bring along the transfer of technology, scientific and development activities to developing countries as well as an increase of finances for the essential drugs;
- industrially developed countries would impose a pressure on the developing countries to apply higher standards than the minimum ones in the TRIPS Agreement.
Concentration characterised by mergers of firms takes place in manufacturing of pharmaceutical products like in other branches of industry. The list of products offered by the new company after merger is often shortened in order to achieve higher competitiveness and fresh challenges to create new products, even if smaller-scale manufacturers continue to manufacture or take over manufacturing of the pharmaceutical products given up by the large firms. This tendency may cause insufficient manufacturing capacity to cover the needs of the global market, subsequently causing a rise in prices. As a rule, manufacturing capacities are insufficient in the manufacturing of patented products for which there is an urgent demand in the countries with less solvent consumers. Unfortunately several HIV/AIDS medicines are among these products. The price rise affects besides less developed countries and developing countries also the USA and the member states of the European Union, especially its new members.

3. Specific Features of the Patent Protection of Medicines

A finished medicinal product in its final container ready for marketing (dosage forms) is usually considered to be a patented medicine, i.e. a product for the end consumer or a bulk product which has completed all processing stages up to, but not including, final packaging. Often an active ingredient protected by the patent is often considered a patented medicine. Actually medicines can be protected in several ways. The TRIPS Agreement (Article 27 Section 1) divides the inventions of all fields of technology into two: products or material objects and processes or activities, each of which has several subdivisions. Most of the processes are actually technological processes or parts of them. Products can be divided into equipment (or apparatus) and substances. In the Patents Acts of many countries the subject of an invention may be the use for new purpose or new application of the known device, substance or process (Kukrus, 1995, p. 24).

The substances as the subject of an invention can be either chemical or biological.

Products such as foodstuffs and spices, cosmetics, medicines etc. also belong to the substances. Chemical substances are divided into individual compounds and compositions. Low molecular compounds and conditionally high molecular compounds belong to the individual compounds. Substances received by traditional biotechnological processes or gene technology methods, including micro-organisms and viruses, belong to the biological materials. The intermediate products of the chemical synthesis are considered protectable substances (Kartus et al., 2001, p. 7).

As a rule, a medicine consists of an active ingredient and an excipient, which is pharmaceutically inert. Types of excipients are binders, fillers, disintegrants, lubricants, coatings, sweeteners, flavours, aromas and colours. An active ingredient with an excipient is called a composition. Different excipients can be used for one active ingredient. On the basis of the same active ingredient it is possible to make different compositions. Different dosage forms of medicines can be made on the basis of the same composition or different compositions.

So, an active ingredient, a composition or a dosage form of medicine, which is new and involves an inventive step, can be the subject of an invention granting patent protection to a medicinal product. To obtain patent protection an active ingredient, a composition or a dosage form should have at least one characterising technical feature to distinguish it from the state of art.
Depending on its kind, the characterising features of the active ingredient of the medicine are its qualitative and quantitative composition, chemical structure or indicators characterising macromolecules, nucleotides and the sequence of aminoacids etc. Qualitative and quantitative composition (a list of ingredients and their amounts) as well as the structure and the composition of ingredients are also characteristic features of a composition. The characteristic features of a dosage form include physico-chemical indicators like the dose, concentration, the state (solid, powdery, liquid, gas) etc.

If an active ingredient of the medicine is the subject of an invention, a composition containing this particular active ingredient as well as a dosage form of medicine made on the basis of the composition containing the active ingredient are protectable. Besides obtaining patent protection of the mentioned substances also a process of getting a new active ingredient, made artificially or separated from nature, and a preparation process of the composition containing the active ingredient and the dosage form of medicine can be patentable as a rule. The use of a new active ingredient in preparation of a composition and a dosage form of medicine means automatically that their preparation process always differs from the state of art by a characterising feature. In some cases a special container or another technical device can be worked out for the application of a particular dosage form of medicine and in this case it is also protectable as an invention in the uniform set with the above-mentioned inventions (Patent Application No EE200300123A, 2005).

Besides the above-described general patent protection principles of the substances applicable to the medicines there are several specific features concerning patent protection of medicines.

The most important specific feature is that any substance, either natural or artificial, can obtain patent protection as a pharmaceutical product only at the first medical use irrespective of the treatment of which disease it will be used for. The following medical use of the same substance or composition for the treatment of another disease cannot obtain patent protection due to the lack of novelty (Examination Guidelines Sec. 2(6), 2004).

Second and further medical use of any substance or composition can be protected by a claim to the use of the substance for the manufacture of a medicine for a specified medical use (Examination Guidelines, Section 4(2), 2004).

Talking about brand-name drugs, generally drugs made on the basis of a new active ingredient are meant. Based on the above, in case of a new active ingredient it is possible to protect not only the active ingredient, but also a composition and a dosage form of medicine and the processes of making the mentioned substances. It can be done separately by selecting only one subject of an invention or altogether forming a uniform complex, applying patent protection for the group of inventions so linked as to form a single general inventive concept (Patents Act, 1994).

Therefore, in case of brand-name drugs their protection is possible by both the product and manufacturing process, which gives a chance to select between the possibilities proceeding from the exclusive right of the patent owner in the market situation. Pursuant to Article 28 Section 1 of the TRIPS Agreement the patent owner has the following rights:
a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of making, using, offering for sale, selling, or importing that product for these purposes for these purposes;
b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using,
offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

4. **Pharmaceuticals Industry during the Period before the TRIPS Agreement**

Enforcement of the TRIPS Agreement made establishment of patent protection compulsory for the pharmaceutical products and processes of making pharmaceutical products to all WTO member countries. It is possible to ensure complex protection to a pharmaceutical product in the patent system corresponding to the requirements of the TRIPS Agreement. Complex protection is possible in case of brand-name drugs. In case of complex protection, the TRIPS Agreement provides an exclusive right in manufacturing and marketing to the owner of the patent.

Before the enforcement of the TRIPS Agreement patent protection for pharmaceuticals as products was not established in many countries. It was established only for the making processes of a pharmaceutical product. The aim of the limited protection system was clearly oriented to the development of pharmaceuticals industry in the country. The impact of the system becomes clear if we take into consideration the fact that in case of lack of protection for the pharmaceutical product as a product copying a pharmaceutical product it is not an infringement of patent law in case the generic drug (the imitation) can be made in a process different from making the brand-name drugs. The process of making a generic drug is usually sufficiently different from the one of making a brand-name drug in order to comply with the criteria of patentability and to obtain patent protection. This principle is the basis of the system enabling to make and protect identical generic drugs fast just after launching brand-name drugs on the market.

The described manufacturing system of generic drugs was used in the majority of nowadays industrially developed countries in order to develop competitive pharmaceuticals industry. Generic drugs were produced until pharmaceuticals industry became sufficiently strong to manufacture brand-name drugs independently. Later the Patents Act was changed and besides process protection also product protection of pharmaceutical products was established. Product protection of pharmaceutical products was established in 1968 in Germany, in 1976 in Japan, in 1977 in Switzerland and in 1978 in Italy (Salazar, 1998). However, product protection of pharmaceutical products was established in Canada comparatively recently - in 1987. Establishment of product protection created chances for financing research and development (R&D) of the pharmaceuticals firms to work out new products. As a result, leading countries in working out new pharmaceutical products appeared and shared the solvent market. The data given in Table 1 illustrate the market shares of brand-name drugs in 1985 across the manufacturers of pharmaceutical products of different countries (Grabowski, 2002, p. 7). The countries in Table 1 belong to the so-called “Nordic” rich industrially developed countries.

Both in the USA and Europe, strong generic drugs industries exist side by side with the manufacturers of brand-name drugs. The manufacturers of generic drugs in the USA have joined the USA Generic Pharmaceutical Association (GPhA). In Europe, the European Generic Medicines Association (EGA) represents the European manufacturers of generic medicines and joins 13 national associations as well as more than 500 manufacturers of generic medicines. The International Generic Pharmaceutical Alliance (IGPA) joins the manufacturers of generic medicines internationally. Besides the above-
mentioned members also the Canadian Generic Pharmaceutical Association (CGPA) and the Indian Pharmaceutical Alliance (IPA) belong to the members of the IGPA.

Table 1. Market Share of Brand-name Drugs

<table>
<thead>
<tr>
<th>Country</th>
<th>The USA</th>
<th>Switzerland</th>
<th>UK</th>
<th>Germany</th>
<th>Sweden</th>
<th>Italy</th>
<th>Japan</th>
<th>France</th>
<th>The others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market share, %</td>
<td>43.4</td>
<td>13.8</td>
<td>9.7</td>
<td>8.7</td>
<td>5.1</td>
<td>4.7</td>
<td>4.1</td>
<td>2.5</td>
<td>8.1</td>
</tr>
</tbody>
</table>

Medicines produced by the manufacturers of generic medicines in the “northern” countries supplement the medicines manufactured by brand-name drug manufacturers, forming even a greater part of the total amount of the drugs on the market, whereas the so-called “southern” poor countries are mainly supplied by the local manufacturers of generic drugs or the other southern countries until now. The leading countries manufacturing generic drugs in this group are India, China, Brazil, Argentina, Thai, Columbia and the Republic of South Africa. The “southern” countries differ from the “northern” countries by that the latter actually lack manufacturing of brand-name drugs so far.

During the period before the TRIPS Agreement, manufacturing of generic drugs in the “southern” countries was based on the lack of product protection of pharmaceutical products like in the industrially developed countries, which have become leading manufacturers of brand-name drugs now. It enabled to copy the brand-name drugs successfully by the “southern” countries and to sell them on the local market and export them to the other poor countries at a relatively low price. This can be illustrated by the example of India, who before the removal of product protection of pharmaceutical products from the Patents Act in 1970 imported most of the pharmaceutical products paying for them almost the highest prices in the world. After the removal of product protection India took a huge leap in the development of manufacturing generic drugs. Presumably it takes the Indian manufacturers of generic drugs 4-5 years to work out the generic drug after launching the brand-name drug on the market (DFID, 2004). After changing the Patents Act, India met the need for drugs of the country and started to export cheap high-quality drugs to poorer countries (Baker, 2005). India and China became the main suppliers of HIV/AIDS drugs in the developing countries. The yearly amount of the anti-retrovirus (ARV) drug costs 10-30 thousand US dollars in the USA and Europe, whereas the generic drug of the first generation made in India costs the patient only 140 (according to some data 250-350) US dollars a year (DFID, 2004). India and China did not export only ready-made drugs but also active ingredients and compositions to the manufacturers of pharmaceutical products in the other developing countries. According to the World Health Organisation (WHO), the price of anti-retrovirus (ARV) drugs made on the basis of the active ingredient imported from India decreased in Brazil by 82% in five years (Cheri, 2004). It is believed that until the enforcement of product protection in 1992 generic drugs formed 97% of the chemically made drugs in China (Hepeng, 2004).

Therefore, developing countries followed principally the same scheme as the industrially developed countries in pharmaceuticals industry before the enforcement of the TRIPS Agreement. The paradox lies in the fact that the industrially developed countries sold generic drugs to relatively soluble local consumers as well as to consumers in the other developed countries and tried to make profit in order to
manufacture brand-name drugs and obtain patent protection in the future, whereas the developing countries had to sell their production on the local market or export it to the countries with less soluble consumers where product protection had not been established for pharmaceutical products. This forced sales in quite large capacities at low price, relieved significantly the lack of drugs of the poor countries, but did not ensure a sufficient profit to the pharmaceuticals industry for research and development for working out and patent protection of the new drugs.

Due to patent protection of pharmaceutical products established by the TRIPS Agreement it is foreseen that almost 700 thousand HIV/AIDS patients (for whose treatment anti-retrovirus drugs made in India were used in the scope of 50%) in the developing countries can be in difficulties. Presumably the Indian and Chinese manufacturers of pharmaceutical products start to prefer richer consumers to the previous developing countries (Pharmaceutical News, 2005).

5. Pharmaceuticals Industry after the Enforcement of the TRIPS Agreement and the Doha Declaration

The same level of patent protection in all the countries was formally achieved by the enforcement of the TRIPS Agreement. This is actually one of the prerequisites of global trade (Cameron, 2004). The manufacturers of brand-name drugs of the developed countries, who had been the initiators and supporters of the TRIPS Agreement, had achieved their indirect aim - a possibility to restrict the market share of the manufacturers of generic drugs bearing in mind the growing demand for them, especially in less developed and developing countries. Undoubtedly HIV/AIDS crises in Africa had an effect on pharmaceutical firms. First, only a remarkably growing demand for the drugs and a chance to make money were seen. Consequently, the developing countries were forced to start action. 39 firms manufacturing brand-name drugs in 1998 initiated a court case against the government of South Africa and the decision of the court was to continue parallel import of HIV/AIDS generic drugs. The principle of free trade is the basis of parallel import. In case of patented products implementation of parallel import depends on how exhaustion of intellectual property rights is regulated. Pursuant to Article 6 of the TRIPS Agreement, the issue of exhaustion of intellectual property rights belongs into the competence of the WTO member, so permitting parallel import of generic drugs is not principally contradictory to the Agreement.

Another debate catching public attention was initiated against Brazil in the WTO by the USA. The government of Brazil had decided to grant compulsory licences to local pharmaceutical firms for manufacturing generic drugs, which were important for the state (Ardagh, 2003, p. 6). Although the principles of the grant of compulsory licences have been described in detail in Article 31 of the TRIPS Agreement, their application causes debates. For example, there is an issue how to treat the grant of a compulsory licence if the main reason for its application is the price of the product as in the case of HIV/AIDS drugs.

In 1999-2001, the expansion of HIV/AIDS epidemic caused an understanding that the TRIPS Agreement had to be revised. In 1999, at the WTO Conference of the Ministers the European Union made a suggestion that the grant of compulsory licences to the drugs belonging into the list of essential drugs should be permitted if a country finds that it is inevitable for public health protection. Although the industrially developed countries did not support the suggestion, the need for making the TRIPS Agreement more flexible was admitted. The TRIPS Council worked hard from April until November 2001 and as a result of it the Doha Declaration on the TRIPS
Agreement and Public Health was passed at the Fourth Ministerial Conference of the WTO Ministers in Doha on 14 November 2001 (WTO, 2001).

The main standpoints in the TRIPS Agreement confirmed by the Declaration were the following:

- Each WTO member has the right to grant compulsory licences to protect public health;
- Each WTO member has the freedom to determine the grounds upon which compulsory licences are granted;
- HIV/AIDS, tuberculosis, malaria and other epidemics constitute a national emergency or other circumstances of extreme urgency.

A decision was made that the TRIPS Council had to find an expedient solution to the problem how countries with insufficient or no manufacturing capacities in the pharmaceutical sector could use compulsory licences to import pharmaceuticals in case of necessity and report to the General Council of the WTO before the end of 2002.

The developing countries and non-governmental organisations (NGOs) approved of the Declaration. The USA thinks that the Declaration is purely political without any legal force. But the European Union evaluates the Declaration as a legal basis for the interpretation of the TRIPS Agreement in the same way by all the member states (European Commission, 2003).

6. The Essence of the Institution of Compulsory Licence

The Institution of Compulsory Licence was established on the basis of the principle of the patent law – the requirement of compulsory implementation of the patented invention. In accordance with the Paris Convention (Article 5A), the Patents Acts of most of the countries include provisions which obligate the patent owner to use the invention independently in the country, or grant a licence to the entrepreneur of the relevant country for the use of its invention. If the patented invention is not used during the period prescribed in the law, any interested person has a right to demand the grant of the compulsory licence under certain circumstances. Therefore a compulsory licence means a permit to use a patented invention issued by a competent authority (in most cases by an authorised state institution) with payment of a royalty or other adequate remuneration to the patent owner. Differing from the ordinary licence, where the parties (a licensor, a patent owner and a licensee) agree upon the right to use, purchase and sell under certain circumstances fixed in the licence agreement, a compulsory licence is granted without the consent of the patent owner on the basis of the court decision (seldom a decision of the patent office). These instances determine the amount of the remuneration to be paid to the licensor (patent owner), the using conditions of the invention and the terms. For example, pursuant to Article 47 Section 1 of the Patents Act of the Republic of Estonia, a person who is interested in using a patented invention and is capable of doing so in the Republic of Estonia, may, upon refusal of the patent owner to grant a licence, file an action in court for acquiring a compulsory licence if:

1) the patent owner has not used the invention in the Republic of Estonia within three years after publication of the notice concerning the issue of the patent or within four years after filing a patent application, and in such case the term which ends later shall apply;

2) the patent owner does not use the invention in the extent which would correspond to the needs of the domestic market of the Republic of Estonia;

3) the patent hinders the use of another, technically advanced invention significant for the economy of the Republic of Estonia;
4) national defence, environmental protection, public health and other significant national interests of the Republic of Estonia require the use of the invention, including the need to use the invention in connection with a natural disaster or other emergency;

5) the patent hinders the grant of plant variety protection pursuant to the Plant Propagating and Plant Variety Rights Act or use of protected plant variety.

It should be mentioned that a compulsory licence will not be granted if the patent owner imports the product protected by the patent from any state member of the World Trade Organisation in the extent which corresponds to the needs of the domestic market of the Republic of Estonia (Patents Act of the Republic of Estonia, Article 47 Section 1).

In case of a classical compulsory licence there are two main problems preventing the grant of compulsory licences to assist the countries with public health problems. One of them is a condition based on Article 5A Section 4 of the Paris Convention, which is included also in the Patents Act of the Republic of Estonia, according to which a compulsory licence cannot be acquired before the expiry of three years after publication of the notice concerning the grant of the patent or within four years after filing a patent application, and in such case the term which ends later shall apply. The term is obviously too long to apply for a compulsory licence when health protection problems occur, especially in case of epidemics.

Another problem to be solved is a condition prescribed in Article 31 (f) of the TRIPS Agreement, according to which compulsory licences are granted predominantly for the supply of the domestic market. Although due to the word “predominantly” the provision could be interpreted in this way that in some cases a compulsory licence can be granted to manufacture for export, it would be preferable and more useful to express this right explicitly in the international agreement to improve legal certainty. The direct aim of the Doha Declaration is to solve these problems.

7. Implementation Principles of the Doha Declaration

On 30 August 2003, the General Council of the WTO approved a Decision which confirmed the solution worked out in accordance with the Doha Declaration for the interpretation of Article 31 of the TRIPS Agreement on importing pharmaceutical products on the basis of compulsory licence to countries with insufficient or no manufacturing capacities in the pharmaceutical sector (WTO, 2003). It should be explained that in the preamble of the Decision the given solution is called “a system”. This term is often used in the Decision, in the later official documents as well as in other sources. Next the most important working principles of the system will be analysed.

The Decision determines what is meant under the product imported on the basis of a compulsory licence. Pursuant to Section 1(a) the subjects to a licence are not only the dosage forms of medicinal product ready for marketing, but any pharmaceutical product related to the healthcare problems of the developing and the least-developed countries, especially HIV/AIDS, tuberculosis and malaria. These three types of epidemics were most widespread at that time and “bird flu” was not topical. A pharmaceutical product means any product, either a patented product or the one made on the basis of a patented process. It has been separately mentioned that active ingredients of pharmaceutical products are the subjects to a licence. This precision is appropriate as the authorities applying the Decision have different understanding of the
essence and specific features of patent protection in different member states. Diagnostic
kits are also subjects to compulsory licence.

The Decision determines which WTO member states can be importing
countries and exporting countries in the sense of using the system. Although the system
is meant for supplying the least developed WTO member states with necessary
medicines it can be used by all the other member states.

For the use of the system an importing country has to:
• notify the TRIPS Council of its intention to use the system;
• notify the TRIPS Council to which extent the system is intended to be used. The
extent means whether it is used only in case of emergency or in other
extraordinary cases or it is publicly used without commercial purposes;
• notify which products and which amounts are intended to be imported. The
information will be published on the web page of the WTO (WTO
Notifications, 2003). By December 2005 no notifications had been published;
• if it is not the least developed country, verify that the pharmaceutical industry
of the country does not manufacture the necessary product or has insufficient
manufacturing capacities with regard to the necessary product;
• confirm that a compulsory licence for importing has already been granted or
will be granted if the product is protected by the patent in the state.

An exporting country using the system has to notify the TRIPS Council of the
grant of a compulsory licence and its conditions. Besides the data of the licenser, the
data about the products, the amounts of products and the states supplying for which the
licence had been granted and the validity period of the licence agreement should also be
notified. After the grant of a compulsory licence, the exporting country has to pay the
licenser a remuneration, which takes into account the value of the product proceeding
under the conditions of the importing country.

Applying the latter requirement is intended to fix a fair remuneration. In
applying this requirement probably it should be taken into account that in exporting to
poorer countries remuneration should not be risen irrelevantly compared to the other
price components. In case of richer countries the impact of the remuneration may be
bigger.

In addition to the above, an exporting country using the system has to ensure
that:
• the amount manufactured under compulsory licence has to correspond to the
needs of importing country and the total manufactured amount will be exported
to the country which had notified the TRIPS Council about the required
amount. The information will be published on the web page of the WTO
(WTO Notifications, 2003). By December 2005 no notifications had been published;
• production manufactured under compulsory licence should be clearly identified
through specific labelling or marking, e.g. by special packaging, colour or any
other way on the condition that marking would not bring along a too high price
rise;
• before starting to deliver the production it should be notified on the web page
which amounts and where the products will be exported and how they are
specially marked.

The Decision waives an obligation to the member states using the system to
follow to prevent misuse. Importing countries have to pay attention to administrative
capability to ensure the purposeful use of the arriving amounts. Re-export of imported
products to richer countries causes concerns. The Decision prescribes a requirement that
an exporting country has to provide financial and technical assistance to operate the system at the request of the least developed countries.

The practical system of granting compulsory licenses in accordance with the Doha Declaration (described above) was approved of and the statements were made by groups of some countries to opt-out of using the system as importers (The General Council Chairperson’s statement, 2003).

23 countries immediately agreed to opt out using the system as importers. They were Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States. Also 10 candidate states of the European Union at that time - the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia – intended to opt out using the system as importers after the accession. There was an opinion that although the latter states made the decision themselves, it was a requirement of the European Commission and a prerequisite of the accession of these states to the European Union (Consumers International, 2005, p. 4). They agreed to opt out using the system as importers even in case of emergency.

The political position of the European Commission that the states of the European Union do not use the system as importing countries and never apply for a compulsory licence for importing pharmaceutical products can be explained in the following way. The Commission probably proceeds from the fact that there are high living standards in the European Union as a whole and financing of healthcare has been on a satisfactory level so far compared to many other countries. Secondly, there is a strong industry of generic medicines in the European Union, which is considered to be capable of meeting the needs of the internal market of the European Union. Thirdly, in principle the Commission does not want to weaken the strong legal protection of inventions and the other industrial property with favouring compulsory licences and so the interests of the manufacturers of brand-name medicines are also protected. Fourthly, the European Union is the initiator of working out this system and has defended it at the WTO.

Hong-Kong, China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, Turkey and the United Arab Emirates also agreed to opt out the use of the system, except in case of national emergency. The statement made by the above-mentioned countries, which takes into consideration the possibility of a case of emergency, should be regarded as a means of precaution and taking into account the possibility of “the bird flu” epidemics it could even be regarded as long-sightedness. In case of extremely widespread epidemics there can be a situation where the price is not the only determinant, but also manufacturers of the brand-name medicines are not capable of meeting the demand of the whole global market. In this case a need for importing generic medicines or even imitations of the medicines of the other manufacturers may arise.

8. Implementation of the Doha Declaration in the European Union

After the adoption of the Decision on the implementation of Paragraph 6 of the Doha Declaration by the WTO General Council on 30 August 2003, the European Commission started to work out a corresponding system for the member states of the European Union on the basis of it. On 29 October 2004, the Commission completed a relevant proposal for a Regulation of the European Parliament and of the Council (the
European Commission, 2004). Its goal is to ensure equal conditions at the grant of compulsory licences for export of pharmaceutical products on the territory of the European Union in order to avoid distortions of competition with regard to the European Union single market operators. The second goal is to apply uniform rules to prevent re-import of pharmaceutical products made on the basis of compulsory licence to the territory of the European Union. The Regulation intends to achieve the efficiency and in case of emergency, fast export of pharmaceutical products to the countries with healthcare problems.

There are two obstacles complicating working out and application of the uniform system of the grant of the compulsory licence for the European Union:

- there exists a territorial patent system independent from the other states in all the member states of the European Union, which means that if an invention enjoys patent protection in one state it does not have it in another state;

- different competent authorities grant compulsory licences in different EU member states. In some states this is a governmental authority, e.g. a patent office, in the other states a court.

In both cases there is a fundamental legal problem. In the first case a problem may arise in the situation where the European Community does not have a uniform patent system enhancing all the EU member states. If a generic medicine is manufactured in a member state where the medicine does not have patent protection, nobody has a right to ask the manufacturer of generic medicines to own a compulsory licence or to apply for a compulsory licence for manufacturing and exporting the pharmaceutical product. Besides, on the basis of the Patent Law it is impossible to prevent re-import of the pharmaceutical product back to the European Union through a country where the pharmaceutical product does not have patent protection. Consequently the European Community Law should be used as the basis for banning re-export of generic medicines. Articles 95 and 133 on the operation of the internal market and uniform trading policy of the Treaty on the Establishment of the European Community (EU Treaty, 2002) are referred to in the preamble of the draft Regulation. Article 133 Section 1 determines that the common commercial policy of the European Community is based on the uniform principles in changing tariff rates, conclusion of customs and trade agreements, achievement of uniformity in measures of liberalisation, export policy and protection measures of trade, e.g. the ones which are required in case of dumping or subsidies. In the present case the Community competence on leading uniform export policy and establishing customs and trading protection measures is used to create a legal basis for prevention of re-import.

On the other hand, the fact which complicates working out of the uniform system is that in case of state authorities their activities in granting compulsory licences are under the jurisdiction of administrative procedure and in case of a court in accordance with the court procedure.

The state authorities have a possibility at their own discretion, depending on the situation, with their administrative decisions to determine necessary measures, keep records, inspect etc.

In case of a court, the whole procedure and decisions have to be based on the legal norms fixed in certain legal acts. A court has remarkably more limited possibilities to design different means at its own discretion than a state authority. Therefore it is complicated to fix the legal norms precisely in the Regulation, which would be applicable in all authorities granting compulsory licences. As administrative procedure and court procedure cannot be harmonised to have a uniform procedure for all the
states, so the not uniform issues were delegated to the member states to be regulated by their national legal acts.

9. **Specific Features of Compulsory Licensing of Pharmaceutical Products in the European Union**

In the European Union, the order of compulsory licensing of pharmaceutical products manufactured for export to countries with healthcare problems will be established by the European Parliament and Council Regulation, which is based on the TRIPS Agreement, the Doha Declaration and the Decision on the Implementation of the Doha Declaration adopted by the General Council of the WTO on 30 August 2003, but there are some essential specific features. Next we are going to analyse the most important provisions of the draft regulation (on 1 December 2005, the European Parliament approved the Commission proposal).

The goal of the Regulation is provided in Article 1, i.e. to establish a procedure for the grant of compulsory licences by patents and supplementary protection certificates (Council Regulation No (EEC) 1768/92) concerning the manufacturing and sale of pharmaceutical products, when such products are intended for export to countries with public health problems. The specific feature of this Article is that although supplementary protection certificates have not been mentioned in the Decision of the General Council of the WTO adopted on 30 August 2003, they provide the invention patent protection equal to patent protection at the expiry of patent protection for a certain period of time and therefore their inclusion is well grounded.

With regard to this Article it should be mentioned that the original text prescribed the use of the system only in case of the importing WTO member. During the developing process of the Regulation, the absolute majority of countries took a position that application of the Regulation should be extended also to the importing countries which are not members of the WTO. Making such a decision was ethically easy, but legally extension of the application of the Regulation arose doubts. A conclusion was drawn that in case of countries which are not members of the WTO, the TRIPS Council could not take administrative obligations such as receiving notifications related to compulsory licences and gathering data. The European Commission has to take these obligations (Article 4a).

Article 2 defines a pharmaceutical product, a right holder, an importing country and a competent authority. In the Regulation “a pharmaceutical product” means any product of the pharmaceutical sector, including medicinal products, active ingredients and diagnostic kits *ex vivo* as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council. The owner of the patent and the owner of supplementary protection certificate are the right holders. In the definition of “an importing country” in the original text it was intended to include the name of the WTO member, but with regard to the Decision to extend the circle of importing countries “an importing country” was defined as a country to which the pharmaceutical product was to be exported, it meant a country to which exporting is legal according to the Regulation. The conditions to which such a country has to correspond are set out in the following provisions. “A competent authority” means any national authority having competence to grant compulsory licences under the said Regulation in a European Union member state. This definition resembling tautology means that every country is competent to decide which authority will grant compulsory licences. The other
authorities in the Regulation (e.g. an authority mentioned in Article 12) are not considered competitive authorities.

In Article 3 an additional precision is made in the definition of a competent authority, whereas competent authorities are the same authorities which have competence for the granting of compulsory licences under national patent law, unless the relevant member state determines otherwise. According to this provision, a competent authority has to be determined by the Patents Act and the European Commission should be notified of the designated competent authority.

Articles 4 and 4a determine the countries which have the right to apply for medical products manufactured under compulsory licence or pharmaceutical products in the broader sense from the European Union. These are:

a) least developed countries in the United Nations’ list;
b) any other member of the WTO which is not in the above-mentioned list, but notifies the Council for TRIPS of its intention to use the system in whole or in a limited way;
c) any country that is not a member of WTO but is listed in the OECD’s Development Assistance Committee’s list of low-income countries (GNP per capita less than 745 USD), and has made a notification to the Commission of its intention to use the system as an importer in whole or in a limited way. This country has to state in the notification to the Commission that it will adopt all the measures in the Decision adopted by the General Council of the WTO on 30 August 2003.

A provision belonging to Article 4 states that if a country which as a WTO member has made a notification to the WTO that it does not use the system as an importing WTO state, this country will not be considered an importing WTO member state in the sense of the Regulation (p. b). Such countries cannot make use of the system. Nowadays Estonia with 32 countries which have made a relevant notification, is among these countries.

Article 5 sets the requirements to the application for compulsory licence. Section 1 prescribes that any person may submit an application for compulsory licence to a competent authority in the member state or the states of the European Union, where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.

Next it is explained which data should be included in the application. These are the data usually required for concluding an agreement, i.e. the data of the applicant and his representative, the name of the pharmaceutical product, the amount of the pharmaceutical product manufactured for export, the importing countries, evidence that he has had prior negotiations with the owner of the patent in accordance with Article 7, which is also one of the requirements of Article 31 (b) of the TRIPS Agreement, and the amount required by the importing country. If exporting of pharmaceutical products is intended to different countries, the amounts should be notified separately for every country. During the working out process of the regulation, an understanding was achieved that if an importing country is incapable of determining the required amount for itself, also non-governmental authorities or the UN organisations or other international healthcare organisations can do it for the country.

There is an incomprehensible and curious fact that the European Parliament found it necessary to exclude from the compulsory data of the compulsory licence the data on patents and supplementary protection certificates required in Article 5 Section 3 of the original text.
As it is well known, particular patents and supplementary protection certificates are subject to a licence agreement. According to the preamble of the Regulation, a member state has a right to prescribe a requirement on submitting data on patents and supplementary protection certificates as a formal requirement of the application.

Article 6 prescribes first that it is the obligation of the competent authority to check if the country where the pharmaceutical products are intended to be exported to, corresponds to the requirements of an importing country in accordance with the Regulation. Secondly, it has to be checked whether the quantity to be exported and the quantities exported earlier from the same country or the other countries do not exceed the quantities needed by the importing country. Both means are meant to prevent granting compulsory licences for manufacturing in ungrounded capacity and in case of exceeding amounts there can be malpractice cases.

Article 7 prescribes the requirements for the prior negotiations of the owner of the patent. A compulsory licence can be applied for if within 30 days efforts to agree with the patent owner upon obtaining an ordinary licence have not been successful. Negotiations are not compulsory in case of use by the government in a situation of emergency or other circumstances of extreme urgency in accordance with Article 31 (b) of the TRIPS Agreement.

Article 8 prescribes the requirements of a compulsory licence, which principally follow the requirements of Article 31 of the TRIPS Agreement, like generally a non-exclusive licence which cannot be transferred, excluding in case of transfer with an enterprise, a well grounded manufacturing capacity and the validity of the licence etc. Special marking of products and packaging as well as special colouring/shaping are prescribed to facilitate clear identification and the custom offices should be notified about it. Besides, before exporting the amounts and destinations should be notified in the Internet. Article 8 includes the basis for payments prescribed in Section 9 in case of use by the government in a situation of emergency or other circumstances of extreme urgency. In this case, a royalty is up to 4% of the price of the product paid by the importing country or for it. In the other cases, the value of the product in the importing country and the fact that generally it is human aid should be taken into account. The European Parliament would have liked to oblige the Commission to work out a uniform methodology of calculating the payments enhancing all situations, but gave up the idea, as the task was too complicated.

Article 9 prescribes the basis for the refusal of the application for a compulsory licence if any of the conditions set out in Articles 5 to 7 are not met or if the application does not contain the elements necessary to allow the competent authority to grant the licence in accordance with Article 8.

Article 10 stipulates that in case of the member states of the European Union the Council for TRIPS should be notified through the intermediary of the Commission and determines which data on compulsory licence should be notified to the Commission.

Article 11 is one of the most essential ones in the Regulation as it prohibits import into the European Union of products manufactured under the Regulation and the Decision of the General Council of the WTO adopted on 30 August 2003 for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse. Only import for the purpose of transit is allowed if the production corresponds to the requirements regarding an exporting country (marking, amount etc). Mentioning the Decision of the General Council of the WTO in the Regulation means that it is prohibited to let pharmaceutical products
manufactured under compulsory licence in any other country in accordance with the Decision to the territory of the European Union and it was included in the Regulation at the request of the European Parliament.

Article 12 prescribes presumably suspension or detention and the period of suspension or detention of the products prohibited by this Regulation by the customs. Suspension or detention, the period of suspension or detention (10 +10 days) and the release are harmonised by the general principles of border measures applied by the customs in the European Union, including seizure and destruction of the prohibited goods.

Pursuant to Article 13, travellers may have an amount of medicines for their personal use, not for business purpose.

Pursuant to Article 14, the patent owner or licenser has the right to demand termination or review of a compulsory licence if the licence conditions are not respected. Termination of the licence can be demanded in an importing country. In case of termination of a licence it is possible to demand the licensee to transport the existing products to an importing country or their destruction depending on the situation. In case an importing country notifies of the need for a supplementary amount of medicinal products, a competent authority may increase the amount prescribed by a compulsory licence without the negotiations with the licenser, if the supplementary amount does not exceed 25% of the originally prescribed amount.

Pursuant to Article 15, appeals related to a compulsory licence against the competent authority are under the jurisdiction of the member state. It should be taken into account that the adopted decision has to have suspensive effect.

Article 16 prescribes which legal acts of the European Community should be taken into account in ensuring the quality of exported pharmaceutical products.

Article 17 prescribes that the European Commission has to notify the European Parliament, Council and the European Economic and Social Committee on the operation of the Regulation every three years after the enforcement of the Regulation. Since the enforcement of the Regulation, the system for exporting on the basis of a compulsory licence, based on the Doha Declaration, in the European Union and its main specific features are as follows:

- both patents and certificates of supplementary protection are the subject for a licence;
- in case of public health problems any products of the pharmaceutical sector can be exported, incl. medicinal products, active ingredients and diagnostic kits \textit{ex vivo};
- extension of importing states which are not members of the WTO;
- exclusion of the member states of the European Union from the states importing on the basis of a compulsory licence;
- keeping records of licence agreements and amounts to be exported;
- strict re-import control.

The goal of the system is to keep the balance between the interests of the manufacturers of brand-name medicines and generic medicines in Europe.

10. Implementation of the Doha Declaration in the Other Countries

Norway, Canada and India have improved their Patents Act according to the Doha Declaration and the decision made by the General Council of the WTO on 30 August 2003. Amendments will be made in the Acts of Switzerland and the Republic of Korea.

Norway was the first to make amendments in the law on 14 May 2004, which enabled to put into practice the decision of the General Council of the WTO. The amendments entered into force on 1 June 2004 (Notification, 2004). Amendments were made in the Patents Act as well as in the Regulation. The provisions of compulsory licences in the Patents Act were fully harmonised with Article 31 of the TRIPS Agreement. The Competition Authority and the courts have been given the authority to grant compulsory licences. An administrative decision of the Competition Authority may always be challenged before the courts. The system given in the Decision of the WTO General Council was implemented by adding new paragraphs 107–109 to the Regulations belonging to the Patents Act.

Norway considers extension to the countries which are not WTO members, the most important specific feature of its system. Another essential specific feature is that Norway has strict requirements of marking and labelling the products and a corresponding attitude to those who do not respect the licence agreement in manufacturing and exporting. Although Norway stated that it does not have many possibilities to actually make a contribution to assist the countries with health problems, it was the first country to set an example both to those providing and receiving assistance, in implementing the system in other countries.

Canada was the second country to make amendments according to the decision of the General Council of the WTO. An Act to Amend the Patent Act and the Food and Drugs (Bill C-9) was passed by the Parliament of Canada on 13 May 2004 (House of Commons of Canada, 2004) and entered into force on 14 May 2005. Although the system established by the amendments corresponds to the Decision of the General Council of the WTO, it includes provisions which have been severely criticised both before and after passing.

First, differently from Norway and the European Union the Canadian Law does not include the definition of exported products, but it prescribes that the list of particular pharmaceutical products has to be determined. The government has the right to amend and change the list, but first it takes time and secondly, a dispute always arises with the manufacturer of brand-name medicines who does not want to enter its pharmaceutical product into the list.

The law in Canada like in Norway and the European Union prescribes that the system extends to the least developed and developing countries, which are not WTO members. At the same time there is a restriction that export on the basis of a compulsory licence into the above-mentioned countries can be done only in case of emergency. In determining an importing country Canada takes into account the applications made by a group of countries to the WTO to opt out using the system as importers. It means that the member states of the European Union, including Estonia, cannot import Canadian pharmaceutical products under compulsory licence.

Despite its deficiencies the Canadian system has been an example to the European Union in determining a 30-days period of prior negotiations with the patent owner and establishment of 4% royalty.

India is one of the most important suppliers of the least developed countries and the countries with insufficient or no manufacturing capacities with pharmaceutical products. Nowadays there are more than 20 thousand pharmaceutical firms in India (Co et al., 2005). That large number of pharmaceutical firms is possible due to the fact that there was no product protection of pharmaceutical products in India until January 2005. Actually 70% of the total production of pharmaceuticals is produced by 250 top firms in
terms of manufacturing capacities, whereas 30% is produced by top ten firms. Proceeding from the TRIPS Agreement, a “mailbox” system was used in India from 1995 until 2005. During this period India received approximately 9 thousand patent applications for pharmaceutical products, which had to wait for the enforcement of the product protection. A firm manufacturing generic medicines can freely continue manufacturing during the period the patent application is in the “mailbox”. Only after the grant of the patent it is necessary to acquire an ordinary licence or a compulsory licence to continue manufacturing the pharmaceutical product (MSF, 2005).

Together with the amendments made in 2005 also Article 90.1 of the Patents Act was amended by adding subsection (vii), which includes provisions prescribed by Article 31 (f) of the TRIPS Agreement and the provision that the licensee can export a patented product (The Patents (Amendment) Act, 2005). There is one condition that the proprietor of the patent has not granted a licence during reasonable time and the market to be exported is not “being supplied or developed” (Article 84 (7)(a)(iii)) (The Patents (Amendment) Act, 2002). Besides a new Article 92A (1) was included in the Patents Act, which gave a right to grant a compulsory licence for exporting pharmaceutical products to countries with insufficient or no manufacturing capacities in accordance with the Doha Declaration. The definition of the pharmaceutical product corresponds to that given in section 1(a) of the Decision of the General Council of the WTO adopted on 30 August 2003.

Nowadays presumably about 70% of 25 thousand HIV/AIDS patients in 27 countries use generic medicines made in India. The lack of product patents enabled the manufacturers of generic medicines of India to make so-called fixed-dose combinations (FDCs) of antiretroviral drugs, which are combinations of pharmaceutical products of different manufacturers. Advantages of using FDCs are convenience, reduction in prescription errors, and easier delivery of treatments.

Enforcement of product protection in India causes concerns in many least developed countries, which do not have to establish protection for pharmaceutical products before 2016. Due to widely spread avian influenza (popularly known as "the bird flu") the government of India intends to grant a compulsory licence to manufacture anti-flue medicine Tamiflu of the known brand-name medicines firma Roche for domestic use as well as export.

Pursuant to Section 11 of the Decision of the General Council of the WTO adopted on 30 August 2003 it is intended to amend the TRIPS Agreement on the basis of the system as a provisional fast solution included in the Decision (WTO, 2005, IP/C/38, p.3). The first document on the amendments was compiled by the African Group in December 2004 (TWN, 2004). Several procedural changes were made to facilitate the system provided in the Decision. Formally the proposal of the African Group meant to amend Article 31 of the TRIPS Agreement with Section 2, which would include all required provisions of the Decision. The European Union also worked out its standpoints. According to later developments, the TRIPS Agreement was amended by inserting Article 31bis, including the most important provisions of the Decision, and by inserting an Annex after Article 73, including the rest of the mainly application provisions. The amendments of the TRIPS Agreement were adopted by the Decision of the General Council of 6 December 2005 (IP/C/41) and approved by the WTO Ministerial 6th Conference on 13-18 December 2005 in Hong-Kong.

African countries and the other developing countries are concerned because of the obstacles the amendments may cause in the availability of pharmaceutical products. The USA agrees to make a compromise, although it does not approve of creating an opportunity to get a compulsory licence for export in the TRIPS Agreement. The
The proposal of the European Union was to confirm the earlier applications of the member states that none of them is eligible importing country. Therefore the list of the member states of the European Union has been replaced by the list of the European Community. This list includes the member states of the European Union who do not intend to import pharmaceutical products on the basis of a compulsory licence (opt-out states), as well as Australia, Canada, Island, Japan, New Zealand, Norway, Switzerland and the USA.

Recently there are doubts as to whether opt-out serves the purpose of taking it as a purely political decision, which could be dangerous from the viewpoint of public health, especially keeping in mind the danger of “the bird flu”. Consumers International has submitted a warning in its notification made to TRIPS Council on 25 October 2005 (Consumers International, 2005, p. 4). There is a great concern about the new members of the European Union. The USA Members of Congress Henry A. Waxman, Sherrod Brown and Thomas H. Allen have expressed their similar concern about the USA in their letter to the USA Trade Representative on 5 December 2005.


In Estonia pharmaceutical products are protected by patents since the enforcement of the Patents Act of the Republic of Estonia on 23 May 1994. Proceeding from the transitional provisions (Article 61 Section 5) Estonia could protect pharmaceutical products on the basis of patent applications, the priority date of which was not earlier than 20 August 1990. Provisions concerning a compulsory licence in Article 47 of the Patents Act correspond to Article 31 of the TRIPS Agreement. There is one important difference - the word “predominantly” is not used in Article 47 Section 1 (2) of the Patents Act, which enables to grant a compulsory licence to manufacture for exporting on the basis of Article 31(f) of the TRIPS Agreement. As a member state of the European Union Estonia does not have a possibility to import pharmaceutical products on the basis of a compulsory licence and therefore, manufacturing of generic medicines is practically excluded and their import is strictly restricted. Import is possible only if there is no patent protection or there is a licence from the manufacturer of the brand-name medicine. Therefore, Estonia cannot create its manufacturing of generic medicines. In the nearest future Estonia will stay among the states without pharmaceutical industry. Estonia cannot import generic medicines even in case of emergency.

Today HIV/AIDS is the most serious problem in Estonia. On 9 December 2005, HIV was diagnosed in 5035 cases and the number of infected people was 593 in Estonia (Tervisekaitseinspektsoon, 2005). In 2004, the number of people with the diagnosis of HIV was 55 to 100 thousand inhabitants, which is 0.55% of the population. In comparison to the data given in Table 2, this number is similar to that of North- and Latin America as well as South-West Asia (UNAIDS, 2004).

According to the Ministry of Social Affairs it is considered an epidemic in the circumstances of Estonia (Sotsiaalministeerium, 2005). According to the HIV estimates, the number of patients needing treatment will increase from 250 in 2005 to 3000 in 2008 (Figure 1). The total expenditure on ARV medicines will increase from 11 million kroons in 2005 to 192 million kroons in 2008 (Figure 2).
Table 2. Number of HIV/AIDS Patients according to Regions in December 2004

<table>
<thead>
<tr>
<th>Region</th>
<th>HIV/AIDS patients (Adults and children (million))</th>
<th>Percentage of the population (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>1.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Caribbean region</td>
<td>0.440</td>
<td>2.3</td>
</tr>
<tr>
<td>Latin America</td>
<td>1.7</td>
<td>0.6</td>
</tr>
<tr>
<td>Western Europe</td>
<td>0.610</td>
<td>0.3</td>
</tr>
<tr>
<td>Eastern Europe and Central Asia</td>
<td>1.4</td>
<td>0.8</td>
</tr>
<tr>
<td>Far East and Pacific Ocean region</td>
<td>1.1</td>
<td>0.1</td>
</tr>
<tr>
<td>South and South West Asia</td>
<td>7.1</td>
<td>0.6</td>
</tr>
<tr>
<td>North Africa and the Near East</td>
<td>0.54</td>
<td>0.3</td>
</tr>
<tr>
<td>Sub-Sahara Africa</td>
<td>25.4</td>
<td>7.4</td>
</tr>
<tr>
<td>Australia and New Zealand</td>
<td>0.035</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>39.4</strong></td>
<td><strong>1.1</strong></td>
</tr>
</tbody>
</table>

Figure 1. Prognosis of the Number of HIV/AIDS Patients in Estonia

Source: Ministry of Social Affairs

Figure 2. Expenditures on ARV Medicines in Estonia (million kroons)

Source: Ministry of Social Affairs

In Estonia mainly brand-name medicines are used for the treatment of HIV/AIDS, because most of them enjoy patent protection in Estonia. In Table 3, a comparison between the expenditures on ARV and GDP per patient in the European Union and the Baltic states has been given.
Table 3. Expenditures on ARV in the EU and Baltic States

<table>
<thead>
<tr>
<th></th>
<th>GDP (EUR)</th>
<th>ARV price (EUR)</th>
<th>Ratio GDP/ARV</th>
</tr>
</thead>
<tbody>
<tr>
<td>The European Union</td>
<td>22500</td>
<td>10,000</td>
<td>0.44</td>
</tr>
<tr>
<td>Estonia</td>
<td>7700</td>
<td>5500</td>
<td>0.71</td>
</tr>
<tr>
<td>Latvia</td>
<td>5800</td>
<td>6500</td>
<td>1.12</td>
</tr>
<tr>
<td>Lithuania</td>
<td>6200</td>
<td>6500</td>
<td>1.05</td>
</tr>
</tbody>
</table>

Source: European Commission

The annual budget of health insurance forms approximately 5% of the Estonian GDP, the average indicator of the European Union is more than 7%. Taking into account the amount of GDP per person, the deficit in pharmaceutical products is significantly bigger than the percentage could suggest. Expenditures on pharmaceutical products and treatment per person in Estonia are on the average 6 times smaller than in the European Union and compared with the leading countries, even 10 times smaller (Eesti Kindlustusseltside Liit, 2003, p. 6). At the evaluation of the European Commission the optimal ARV expenditures per patient in Estonia are 2000-3000 euros (31-47 thousand kroons) taking GDP into account.

Bearing in mind that there is no pharmaceutical industry in Estonia capable of making generic medicines, the following possibilities for reducing the price of HIV/AIDS medicines to the desired level are:

- compulsory licence for importing generic medicines in accordance with the Doha Declaration;
- parallel imports of the brand-name medicines or generic medicines from the country belonging to the European Economic Area;
- price negotiations with the manufacturer of brand-name medicine;
- import of generic medicine by the order of the government with payment of compensation to the manufacturer of brand-name medicine (the patent owner in Estonia).

Based on the above we can see that in the case of Estonia it is impossible to import pharmaceutical products in accordance with the Doha Declaration because Estonia gave up the status of importing country. If amendments to the TRIPS Agreement are adopted, the agreement to opt out using the system as importers individually declared by the member states of the European Union will be replaced by opt-out agreement by the European Community as a whole and there will not be even a theoretical possibility to withdraw the individual declarations of the EU member states.

Parallel import of brand-name medicines or generic medicines from another country belonging to the European Economic Area, from where it is possible to supply at a lower cost, is in accordance with the Patents Act of the Republic of Estonia (Article 171 - Exhaustion of rights), the law of the European Union as well as the TRIPS Agreement. The problem is the availability of cheaper pharmaceutical products at a favourable price and in a needed amount in the countries of the European Economic Area.

Proceeding from the requirement of equal competition conditions on the domestic market of the European Union, pharmaceuticals firms cannot offer favourable prices to some countries and this fact should be kept in mind during the price negotiations with the manufacturers of brand-name medicines. Importing generic medicines by the order of the government means importing outside the institution of
compulsory licence. Although the provisions of Article 31 Section b of the TRIPS Agreement are the basis of the system of granting compulsory licences in accordance with the described Doha Declaration, this provision does not include a requirement that there has to be a licence agreement for importing pharmaceutical products in case of national emergency or other circumstances of extreme urgency. In case of Estonia it is impossible to grant a compulsory licence for importing pharmaceutical products and therefore a parallel system should be worked out to ensure public health and security of the state.

12. Conclusions

Nowadays patenting of new products is more important in pharmaceutical industry than in the other branches of industry related to high technology. Concentration of manufacturing takes place in pharmaceutical industry as well as in the other branches of industry and it may bring along insufficiency of some products to meet the needs of the global market. As a rule, production capacities are insufficient with regard to patented products and for which there is high demand in the countries with less soluble consumers. Medicines for the treatment of HIV/AIDS, tuberculosis, malaria and recently also “the bird flu” belong to such products.

Enforcement of the TRIPS Agreement made patent protection for pharmaceutical products and processes of making pharmaceutical products compulsory to all WTO member states. The same level of patent protection was formally achieved by the enforcement of the TRIPS Agreement in all countries, which is actually one of the prerequisites of the global economy.

In 2001, the Doha Declaration on the TRIPS Agreement and Public Health was adopted. For the implementation of Chapter 6 of the Doha Declaration the European Commission started to work out a Regulation to create a corresponding system in the European Union. The goal of the Regulation is to ensure equal conditions to grant compulsory licences for exporting pharmaceutical products on the territory of the European Union and apply uniform rules to prevent re-import of pharmaceutical products manufactured on the basis of compulsory licences to the territory of the European Union.

As a member state of the European Union Estonia does not have a possibility to import pharmaceutical products on the basis of a compulsory licence and therefore manufacturing generic medicines is practically excluded. Nowadays Estonia spends 5500 euros a year on treating a HIV/AIDS patient with brand-name medicines. Taking into account the Estonian GDP the sum should not exceed 2000-3000 euros. As in Estonia it is impossible to apply for compulsory licences for importing generic medicines in accordance with the Doha Declaration, there are the following possibilities for reducing the price of medicines:

- parallel imports of the brand-name medicines or generic medicines from the country belonging to the European Economic Area;
- price negotiations with the manufacturer of brand-name medicine;
- import of generic medicine by the order of the government with payment of compensation to the manufacturer of brand-name medicine.

Parallel import of brand-name medicines or generic medicines from another country belonging to the European Economic Area, from where it is possible to supply at a lower cost, is in accordance with the Patents Act of the Republic of Estonia (Article 17 Exhcession of rights), the law of the European Union as well as the TRIPS
Agreement. The problem is the availability of cheaper pharmaceutical products at a favourable price and in needed quantities in the countries of the European Economic Area.

The use of parallel imports of medicines may be inefficient in case of brand-name medicine protected by the patent as the price level of such medicines in the different countries of the European Economic Area is not remarkably different. During price negotiations it should be kept in mind that the requirement of equal competition conditions does not enable to offer favourable prices to some countries. Importing generic medicines by the order of the government means importing outside the institution of compulsory licence. As Article 31 of the TRIPS Agreement does not prescribe that in case of national emergency or other circumstances of extreme urgency there has to be a licence agreement for importing pharmaceutical products, in Estonia a parallel system should be worked out to enable importing of generic medicines, for example in case of the possible „bird flu“ epidemic.

References


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