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Parallel trade in pharmaceuticals

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Abstract

This dissertation was written as part of the LLM in Transnational and European Commercial Law, Mediation, Arbitration and Energy Law at the International Hellenic University.

In this dissertation, there will be analyzed the phenomenon of parallel trade in pharmaceuticals, which is based on the principle of parallel trade in pharmaceuticals, according to Articles 34, 35 and 36 TFEU, as mentioned in the first chapter.

Moreover in the second chapter, there will be an analysis for the pharmaceutical market and the parallel trade in pharmaceutical sector. In the same chapter, there will be mentioned which is the importance of intellectual property rights in pharmaceutical industry and, also, which is the meaning of Exhaustion of Intellectual Property Rights. The subsequent chapter refers to Articles 101 and 102 TFEU and the restraints in parallel trade of pharmaceutical products, which is an issue examined in many ECJ law-cases, some of which are mentioned to the fourth chapter. Finally, the last chapter has to do with positive and negative aspects of parallel trade in pharmaceuticals.

Keywords: parallel, pharmaceuticals, competition, free, goods

Anna Siokou
16-2-2018

Preface

Hereby is my dissertation “Parallel Trade in Pharmaceuticals” that has been written to fulfill the graduation requirements of the LLM in Transnational and European Commercial Law, Mediation, Arbitration and Energy Law at the International Hellenic University.

The research was difficult, but the bibliography gave me the opportunity to analyze all the crucial issues that have to do with the phenomenon of parallel trade in pharmaceuticals.

I would like to thank especially my supervisor Dr. Thomas Papadopoulos for his guidance and wonderful cooperation. Without the great support of my supervisor, this dissertation could not be completed.

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Introduction

Free movement of goods is one of the most important principles that has been established in European Union, according to Articles 34, 35 and 36 of the Treaty on the Functioning of the European Union. This is why the same Treaty provide a lot of provisions, such as tax provisions or provisions regarding custom duties, which support free circulation of goods and healthy competitive environment between Member States. Depending on these Articles, it has to be mentioned that parallel trade is a very common phenomenon in pharmaceutical market as well, something that has many effects not only in patients, but, also, in health security systems and pharmaceutical companies around European Union.

More analytically, parallel trade in pharmaceutical sector started at around 1970, but was regulated for the first time in the provisions of the Treaty Establishing the European Community and especially in Articles 28, 29, 30 of the above mentioned Treaty¹. One of the most important reasons that lead to the expansion of parallel trade in pharmaceuticals is the fact that in every Member State there is a different price even for the same product due to the financial ability of the consumers or the regulations of the national health authorities of each country. For example, many times pharmaceutical companies prefer to sell their medicinal products in another Member State, where consumers can afford more expensive drugs, in order to gain higher profits.

To continue with, until today, there has been formulated a specific framework of the pharmaceutical market in European Union which follows the general principle of free circulation of goods within Member States. In more detail, because of the fact that each Member State had its own regulations for the authorization, marketing and sell of a pharmaceutical product, competent European Authorities decided that there should be a specific authorization system for the whole European Union in order to make the process easier for all the traders. On this basis, there was established European

¹ Hancher Leigh "The EU pharmaceuticals market: parameters and pathways" (published 2010) ch 15, 635

Medicines Evaluation Agency (EMA) that is responsible for all the relevant procedures, for all the Member States alike².

At this point, it should be, also, mentioned that intellectual property rights is one of the biggest assets of a pharmaceutical company, because they invest not only a lot of money but also time and intellectual property rights play the role of a motivation for them. This is why it should be examined which is the role of exhaustion of IPRs in the expansion of parallel trade in consumer goods in general and why it allows parallel trade of pharmaceutical products in European Union being a common phenomenon within Member States. It is very important to mention, as well, that because of the fact that parallel traders gain great profits, the manufacturers of the pharmaceutical products sometimes try to restrain traders by parallel importing their products using many methods based on Articles of TFEU. However, it should be examined whether these methods are legal or not. Regarding this issue, there are many ECJ law-cases that have to do with EU Competition Law Rules and parallel trade. In more detail, in these cases, as analysed in this paper, it was examined whether some obstacles put in parallel traders infringe the provisions of Articles 101 and 102 TFEU³, according to which no obstacles should be set in trading between Member States and nothing should prevent competition within EU internal Market.

To sum up, it is without doubt that parallel trade not only, in general, but also in pharmaceuticals specifically, is a very controversial issue that has positive and negative aspects as well. The question which will be the situation regarding parallel trade in pharmaceuticals in some years remains unanswered, because, undoubtedly, in these circumstances of financial crisis, traders try to find the most profitable way to sell their products. However, despite the fact that there are many regulations, directives and agreements between Member States and even more law cases, trying to clarify the legal framework of parallel trade in pharmaceutical products, there are still unclear issues. It remains to be seen which exactly will be the legal framework of parallel trade in pharmaceutical sector in the next decades and also which will be the criteria for the adoption of new principles regarding this issue.

² Kyle Margaret, "Parallel trade in pharmaceuticals: Firm responses and competition policy" (published 2009), 340

³ Articles 101 and 102 TFEU

These crucial subjects will be analysed in this paper, in order to examine in which way parallel trade of pharmaceutical products functions in European Union nowadays.

1. Free movement of goods in EU Internal Market

To start with, in this paper has to be analyzed the principle of free movement of goods, according to Articles 34, 35 and 36 Treaty on the Functioning of the European Union, which allows the parallel trade of consumer goods in internal market and prohibits obstacles in cross-border trade between Member States. As a result it is obvious that the term “goods” plays a major role in parallel trade within European Union. Analytically, “goods” are consumer products that have a monetary value and can be bought and sold⁴.

1.1. Article 34 and 35 TFEU

1.1.1. Analysis of Article 34 and 35 TFEU

It has to be mentioned that single EU Internal Market is one of the most important elements of European Union, because in this way, consumer goods can freely move within the European Union limits. In this framework, parallel trade is allowed within European Union especially according to Articles 34 and 35 TFEU⁵.

More specifically, according to Article 34 TFEU *“Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States”*.⁶ In practice, it means that Member States shall not make harder the process of importation of goods from another Member State and that there should be no quantitative restrictions or measures with equivalent effect, direct or indirect, regarding the transportation of goods between Member States. For example, it is not acceptable, according to Article 34 TFEU, that a Member State asks for an extra license that other Member States do not ask for in order to accept the importation of foreign consumer goods. In other words, there should be no obstacles to trade between Member States, otherwise, the objective of a single market in European Union shall not be implemented.

More specifically, Articles 34 and 35 TFEU do not allow the existence of QRs and MEQRs in cross border trade between Member States, even directly or indirectly. It

⁴ Alina Tryfonidou, “Free movement of goods” (published 16 December 2014), available at <<https://login.westlaw.co.uk>>

⁵ Kyle Margaret, “Parallel trade in pharmaceuticals: Firm responses and competition policy” (published 2009), 340

⁶ Article 34 TFEU

has to be mentioned that the definition for “MEQRS” is different according to the provision that includes it. For our purposes, the term “MEQRS” has to do with any measure that Member States adopt and as a consequence of that, parallel trade becomes even more difficult⁷. Due to this definition which is not precise, there are many ECJ law cases interpreting it, some of which are mentioned below.

1.1.2. Dassonville Case 8/74

In connection with the above mentioned, there have been many disputes and respective case law by the European Court of Justice regarding the meaning of equivalent effect of measures, such as the Case 8/74 Procureur du Roi v Benoit and Gustave Dassonville⁸ (1974), which is one of the most important cases regarding this issue. This EU Law case has to do with the fact that according to Belgian Law Dassonville was required to have a certificate in order to sell Scotch whisky in Belgium, but Dassonville didn't get such certificates from France, where he bought these goods for sale. To analyze it, Belgian Law made the sale of the consumer goods harder for Dassonville, as in France there was no respective measure, which means that Dassonville could easier sell Scotch whisky there. The controversial issue was about whether provisions of Belgian Law infringed Article 34 TFEU, according to which no restrictions, direct or indirect, are allowed in the framework of trade between Member States. ECJ decided that, verily, Belgium should not have stated an obstacle to trading, as it is a measure with equivalent effect to restrictions in quantity. The fact that the obstacle is not very big, is not a criterion for the examination of this issue⁹, because it undoubtedly prevented free circulation of consumer goods.

1.2. Article 36 TFEU

1.2.1. Analysis of Article 36 TFEU

However, according to Article 36 TFEU there are some circumstances such as “...*public morality, public policy or public security; the protection of health and life of humans,*

⁷ See Alina Tryfonidou, “Free movement of goods” (published 16 December 2014), available at <<https://login.westlaw.co.uk>>

⁸ Case 8/74, Procureur du Roi v Benoit and Gustave Dassonville [1974]

⁹ See Case 8/74, Procureur du Roi v Benoit and Gustave Dassonville [1974]

animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property.....¹⁰ that could lead to prohibitions or just restrictions on free movement of goods in European Union¹¹.

Regarding the topic of this paper, the most important justification for the prohibition of cross-border trade between Member States is the “..protection of industrial and commercial property...¹²”. In any case, the protection of intellectual property rights, in general, shall not in any case be a justification for the prohibition of trade between Member States. In other words, from the above mentioned, it is understood that despite the fact that intellectual property is a very serious issue, the principle of free movement of goods shall not be affected and for this reason many directives try to regulate it in order to ensure the proper functioning of the single internal market of European Union.

More specifically, in the framework of parallel trade in pharmaceuticals, it is observed that Article 36 TFEU is sometimes used by Member States that want to ensure that the production of pharmaceutical products by domestic pharmaceutical companies shall not be harmed. However, this behaviour is most of the times opposed to the basic principles of the Treaty on the Functioning of the European Union. The reason is that that the owner of the intellectual property rights shall not prevent others from importing the pharmaceutical product to any other country of the European Union after it was first marketed, because after the first distribution of the pharmaceutical product, all industrial property rights are exhausted. Based on the fact that the most important rights in pharmaceutical industry are the patents and the trademarks, the exhaustion of IPRS plays a vital role in parallel trade of pharmaceutical products and it will be analysed below in this paper.

1.2.2. Cassis De Dijon Case 120/78

Regarding Article 36 TFEU, it has to be mentioned that there are many law-cases, trying to specify the meaning of this provision. One of these is the case Rewe-Zentral

¹⁰ Article 36 TFEU

¹¹ European Commission, Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods (Luxembourg: Publications Office of the European Union, 2010) ch 6, *available at* <ec.europa.eu/DocsRoom/documents/104/.../1/.../pdf>

¹² See Article 36 TFEU

AG v Bundesmonopolverwaltung, known as Cassis De Dijon Case 120/78¹³. The importance of this law case has to do with the fact that it interpreted the term "MEQRS" stating that if the marketing of a good is allowed in a certain Member State without extra requirements, the same will happen to all Member States. An extra requirement could be for example, a certificate mandatory for the trade of a product. This decision was the first time of application of the principle of mutual recognition¹⁴. This law case has to do with the sale of a specific type of the liqueur "Cassis de Dijon" produced in France with a percentage of 15% to 20% alcohol, whereas in Germany there was a law provision, according to which this type of liqueurs should have at least 25% of alcohol. Of great importance is that despite the fact that the competent authorities allowed the importation of goods, the marketing of the specific goods was prohibited in Germany and due to this prohibition the importer stated that it was a measure with equivalent effect to quantitative restriction in the framework of trade between Member States. According to the above mentioned, ECJ decided that the German law provisions set measures, that are equivalent to quantitative restrictions in imports, something that infringes the principle of free movement of goods and especially, Articles 34-36 TFEU, even if the same restrictions are applied not only to the goods imported, but, also, to the consumer goods produced in this country. In this law case the protection of public health and the protection of the buyers incurring commercial practices that are not fair, were not accepted as a reason for the application of such restrictive measures to cross-border trade. As a result, we understand that the application of Article 36 TFEU should be examined every time, because it depends on the circumstances of each case.

1.3. Other Articles of TFEU

1.2.1. Analysis of Article 30 TFEU

Article 30 TFEU plays a vital role in the trade between Member States, as it prohibits custom duties and other similar charges on transactions between Member States. Relating to this issue, there is a huge range of ECJ and other Courts decisions which,

¹³ Case 120/78, Rewe-Zentral AG v Bundesmonopolverwaltung [1978]

¹⁴ See Alina Tryfonidou, "Free movement of goods" (published 16 December 2014), available at <<https://login.westlaw.co.uk>>

furthermore, provide the interpretation of the term CEE defining that CEE are all the charges applying to import or export of goods crossing borders. This kind of charges is not allowed as the effect of them is that foreign goods become even more expensive, and as a result, domestic goods are cheaper and more attractive for the consumers. In other words, CEEs harm the implementation of the principle of free movement of goods¹⁵.

1.2.2. Commission of the European Communities v Italian Republic 24/68

Regarding Article 30 TFEU there is a case known as Commission of the European Communities v Italian Republic 24/68¹⁶. Analytically, Italy imposed a tax - known as statistical levy - before the application of the EEC Treaty, on the imported and exported goods. This tax depended on the weight of the goods, meaning that if a good was heavier than another, the tax for it would be heavier. However, Commission decided that this tax was a measure equivalent to customs, something that was prohibited at that time according to Article 16 of the EEC Treaty, irregardless of how heavy was the tax. Commission justified her decision mentioning that according to the provisions of the EEC Treaty such a charge is not allowed, because it is contrary to the principle of free movement of goods and there are no justifications that the Treaty states or that a Member State could use in order to overlook the relevant provisions of the Treaty. Finally, the Commission stated that there may be cases that Member States could be charged with an amount of money - which is not a tax – when a service is needed in the framework of import or export of goods, but, undoubtedly, this charge may be allowed in specific services that are irrespective of Articles 9, 12, 13 and 16 of the EEC Treaty. According to the above mentioned, the defendant mentioned that Commission's decision was wrong, because that the specific charge cannot be characterized as a charge with equivalent effect to custom duties as this charge is imposed both in imports and exports of not only foreign, but, also, of domestic goods, which means that there is no discrimination. The defendant, moreover, stated that Commission should not have judged the specific charge, dividing it into two different charges, one to the import and one to the export of goods. The answer to this

¹⁵ See Alina Tryfonidou, "Free movement of goods" (published 16 December 2014), available at <<https://login.westlaw.co.uk>>

¹⁶ Case 24/68, Commissioner of the European Communities v Italy 24/68 [1996] ECR 193

argument was that it is irrelevant whether this charge is one general or two different charges, because in any case it has an effect on the free movement of goods.

Based on the above mentioned provision of Article 30 TFEU, it should be mentioned again that when a charge is characterized as CEE it is in any case unlawful and there is no possibility of levying such a charge lawfully. However there are some charges that are not characterized as CEE and for this reason Member States charge others lawfully and especially, charges that have to do with administrative services or inspection mandatory according to the European Law provisions or internal taxation, according to Article 110 TFEU. According to this issue, there is a case known as *Commission of the European Communities v Germany 18/87*¹⁷, which has to do with a charge imposed by Germany upon the import of live animals. The decision was that this specific charge was justifiable as charge for a specific economic service, which is lawful under EU Law.

1.2.2. Analysis of Article 110 TFEU

Although, Article 110 TFEU states that Member States can freely tax all goods marketed within their Territory, they are not allowed to tax directly or indirectly goods imported in their countries, which is something of great importance for the free circulation of goods within European Union. To analyse it more, when a Member State imposes a higher tax in foreign goods imported in their countries, the price of these goods becomes even higher and as a result, consumers prefer to buy similar domestic goods which are cheaper. Article 110 TFEU states taxation prohibitions in both paragraphs¹⁸.

In more detail, according to Article 110 (1) TFEU “..No Member State shall impose, directly or indirectly, on the products of other Member States any internal taxation of any kind in excess of that imposed directly or indirectly on similar domestic products..¹⁹”. It means that discrimination in taxation of goods imported - in the interest of domestic goods – is not allowed, and there should be no justifications, such as the origin of goods or the frequency of import especially in direct taxation. However, there are some certain objective reasons why indirect taxation could lawfully

¹⁷ Case 18/87, *Commission of the European Communities v Germany* [1988] E.C.R. 3595

¹⁸ See Alina Tryfonidou, “Free movement of goods” (published 16 December 2014), available at <<https://login.westlaw.co.uk>>

¹⁹ Article 110 (1) TFEU

be imposed by a Member State in imported foreign goods. Regarding this issue, there is a law-case known as *Chemical Farmaceutical SpA v DAF SpA* 140/79, which has to do with an industrial policy justification. Analytically, in this case there was a difference in taxation between denatured synthetic alcohol and denatured alcohol, but the Court decided that it was not opposed to Article 95 of the EEC Treaty, because the same measure was applied to the two categories of alcohol imported into Italy by all Member States. In any case, imports of synthetic alcohol into Italy were limited and the lower taxation of domestic goods was in favour of Italian production of denatured ethyl alcohol from sugar-beet molasses²⁰.

Furthermore, according to Article 110 (2) TFEU “...no Member States shall impose on the products of other Member States any internal taxation of such a nature as to afford indirect protection to other products..²¹”. It means that it is not allowed to tax differently foreign imported and domestic goods which are in competition, meaning goods that consumers can replace one another, because in this way consumers choose the cheaper product, based on the price of it.

From the above mentioned, it is obvious that Articles 110 (1) and 110 (2) TFEU have similar meaning. The difference between them is that Article 101 (1) TFEU has to do with products similar the one with another, whereas Article 110 (2) TFEU has to do with products that are in competition with each other. As a result, when there is an infringement of Article 110 (1) TFEU, the Member State shall impose equal tax to similar domestic and foreign goods and when the infringement has to do with Article 110 (2) TFEU, the Member State should avoid protecting domestic products by imposing lower taxes in comparison with foreign goods that are in competition with them²².

1.4. Conclusion

To sum up, it is without doubt that the principle of free movement of goods is one of the most important principles in European Union that helps the uniformity and integration of EU Internal Market, according to Articles 34, 35 and 36 TFEU. However,

²⁰ Case 140/79, *Chemical Farmaceutical SpA v DAF SpA* [1981] E.C.R. 1

²¹ Article 110 (2) TFEU

²² See Alina Tryfonidou, “Free movement of goods” (published 16 December 2014), available at <<https://login.westlaw.co.uk> >

there are also other provisions of Treaty on the Functioning of the European Union which support the integration of single European Union Market, such as tax provisions or provisions regarding custom duties in case of import or export of goods within European Market. As it will be analyzed below in this paper, the principle of free movement of goods is the basis of parallel trade in pharmaceuticals within European Union. For these reasons and because of its importance, there are many cases that ECJ dealt with, trying to specify the meaning of the principle of free movement of goods within European Union and generally, of the framework of single EU internal market.

2. Parallel trade in pharmaceuticals

In this Chapter will be analyzed not only the general meaning of parallel trade, but, also, the more specific provisions of parallel trade in pharmaceuticals, a phenomenon which is connected with the existing conditions applying to pharmaceutical market in EU. Moreover, another very important issue mentioned here is the major role that intellectual property rights play in pharmaceutical industry and finally, the principle of exhaustion of intellectual property rights that has to do with the legal framework of re-importation of goods in general and also in pharmaceuticals.

2.1. General meaning of parallel trade

The general meaning of the term “parallel trade” is the resale of consumer goods in other markets without the authorization of the original owner of the intellectual property rights that have to do with these goods, meaning the trademark, patent, design or copyright. In more detail, parallel importing refers to the sale of the same good in different markets at different prices²³. This phenomenon is something well known in European Union. In practice, when the regulations allow it and the movement of consumer goods is economically affordable, firms choose parallel trade and in this way, make bigger profits, because they sell low-price consumer goods in high-price countries²⁴. Additionally, parallel importing encourages not only competition between Member States, but, also, the free movement of goods, according to Article 34 TFEU, while, simultaneously, gives the opportunity to consumers all over European Union to choose the cheapest between more products of the same quality. However, there are people who think that parallel trade harms intellectual property rights and prevents companies in Member States to investigate in new patents and qualitative products²⁵, because companies try to produce cheaper

²³ Kyle Margaret, “Parallel trade in pharmaceuticals: Firm responses and competition policy” (published 2009), 339-346

²⁴ Bart Thomas, “Parallel trade of pharmaceuticals: a review of legal, economic and political aspects”, Value in health (Volume ii, Number 5, 2008) 996

²⁵ Arfwedson Jacob, “Re-importation (Parallel Trade) in Pharmaceuticals”, Institute for Policy Innovation (IPI Center for Technology Freedom, 2004) 1

products at regular intervals in order to gain profit by selling their goods in other Member States.

2.2. The incentives for re-importation of consumer goods

Parallel importing has to do with the fact that someone can find the same consumer good at different prices in various markets. In more detail, companies choose “parallel trade” when the expenses of transportation and sale of consumer goods in foreign countries are lower than the price differential²⁶ and in this way they gain profit easily and of course, lawfully applying the basic principle of free movement of goods within European Union.

However, there are many reasons that lead to the expansion of parallel trade between Member States. First of all, the owner of the intellectual property rights has the ability to sell the good in different prices according to the needs and the financial ability of every market, meaning that the price of the goods is adapted to the special circumstances of every Member State. Furthermore, it is very important that Intellectual Property Rights protection is different in every country and for this reason there may be a case that a product is no longer under protection, because of the expiration of the patent, whereas the same product is protected in another country with different jurisdiction. In this case, in the country which applies the shorter period of patent protection, a company could sale generic products and in this way reduce the price of the patented product. Moreover, the different circumstances of every country and the standard of living may influence the price of the consumer goods, as well as the fact that each government regulates in different way the prices of consumer goods. As a result, it will be a motivation for parallel trade of consumer goods in European Union. Furthermore, it is without doubt that tax system may cause price differentials, because companies try to gain profits using different sales strategies and finally, a circumstance leading to price differentials is the variation of inflation rates depending on the regulation and the circumstances of each country²⁷. So, it goes without saying that price differentials may often be a motivation for the

²⁶ See Arfwedson Jacob, “Re-importation (Parallel Trade) in Pharmaceuticals”, Institute for Policy Innovation (IPI Center for Technology Freedom, 2004) 5

²⁷ See Arfwedson Jacob, “Re-importation (Parallel Trade) in Pharmaceuticals”, Institute for Policy Innovation (IPI Center for Technology Freedom, 2004) 5

traders to choose parallel trade in order to gain profits in an environment, different from the country of origin, which is of greatest benefit for them.

2.3. Parallel trade in pharmaceuticals

2.3.1. Meaning of parallel trade in pharmaceuticals

As mentioned, parallel trade in general has as main goal the maintenance of the unity of EU internal Market and of the competitive environment between Member States. More specifically, parallel trade in pharmaceuticals - based on the free movement of consumer goods, as regulated by European Union - has to do with the parallel importing of pharmaceutical products in Member States, something which has specific implications not only to patients, but also to the health security systems and the pharmaceutical companies as well. Parallel trade in pharmaceuticals started at around 1970, without being specially regulated. However, parallel trade was then established as basic principle of European Union and is until now depended on the free movement of goods, mentioned, initially, in the provisions of Articles 28, 29 and 30 of the Treaty Establishing the European Community²⁸.

2.3.2. Pharmaceutical market in EU

In connection with the above mentioned and in order to examine the expansion of the phenomenon of parallel trade especially in pharmaceutical sector, it has to be analyzed which are the existing circumstances in the market of pharmaceutical products within European Union. As it is known, there are very strict rules regarding the production and the authorization of drugs not only in every country distinctly, but, also, in European Union. At this point, it is very important to be mentioned that because of the fact that every Member State had its own rules regarding the production and sale of pharmaceutical drugs, something that made harder the parallel trade in pharmaceuticals around European Union, there has been many attempts to make the procedures easier and more equable²⁹. More specifically, the application of Directives and the establishment of European Medicines Evaluation Agency (EMA)

²⁸ Hancher Leigh "The EU pharmaceuticals market: parameters and pathways" (published 2010) ch 15, 635

²⁹ Claudia Desogus, "Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel trade" (published 2013) ch 1, 39-42

were the most important steps for the achievement of uniformity³⁰, because, in this way, pharmaceutical companies that do business within European Union follow a certain authorization procedure for the whole EU Internal Market, saving in this way money and time.

However, the most difficult part for the uniformity of pharmaceutical market in European Union is the fact that in every Member State there may be a different price even for the same pharmaceutical product. It has to do not only with the financial ability of the consumers, but, also, with the different regulations that every country has. As a result of the existence of mechanisms that control the prices in every country, pharmaceutical companies choose parallel trade as the most advantageous solution which, as above mentioned, is based on the principle of free movement of goods, according to Articles 34, 35 and 36 TFEU and is lawful as it depends on one of the basic principles of European Union³¹.

2.4. The role of intellectual property rights in parallel trade of pharmaceuticals

2.4.1. Importance of intellectual property rights in pharmaceutical industry

It is without doubt that intellectual property rights such as patents and trademarks play a vital role for pharmaceutical companies in general and are of great value for them. The reason for this fact is that every pharmaceutical company around the world investigates in new pharmaceutical products, something which needs not only much money, but, also, enough time in order to produce a new innovative drug. As a result and based on the great importance of the field of Research and Development for a pharmaceutical firm, it is proved why intellectual property rights is the biggest asset of a pharmaceutical firm³². At this point and in order to emphasize the fact that intellectual rights are the most important assets for pharmaceutical companies, it

³⁰ Desogus Claudia "Competition and innovation in the EU regulation of pharmaceuticals: the case of parallel trade" (published 2010), available at <<http://www.andychinart.com/competition-and-innovation-in-the-eu-regulation-of-pharmaceuticals-the.pdf>>

³¹ See Claudia Desogus, "Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel trade" (published 2013) ch 1, 39-42

³² Alberto Heimler, "The pharmaceutical industry and parallel trade"

should be mentioned that except for the registered IPRS, there are, also, IPRS, for which there is no need for registration³³, such as copyright.

Here will be analysed the meaning of patent, which is the most important kind of intellectual property right in pharmaceutical industry. To start with, patents are the main element for a pharmaceutical company that invests in new drugs and researches, in order to develop new qualitative pharmaceutical products³⁴. The reason, especially for the importance of patents is that on the basis of patent protection the owner of the patent has a long period of exclusivity on the drug³⁵. Of course, the importance of patent protection has to do with duration of the period that a patent is an exclusive right of a specific proprietor. At this point, it is very crucial to mention that according to international agreements the period of exclusivity of a patent is twenty (20) years from the date that the proprietor applied for a patent³⁶. Someone could say that a patent is a reward for pharmaceutical companies that choose to investigate in new drugs and spend money for that aim, instead of trying to save money and sell cheap drugs of poor quality to patients around the world. In other words, when a company produces a new drug, it applies for a patent, in order to ensure that it has a monopoly position in the pharmaceutical industry regarding the specific product³⁷.

However, there are, of course, not only positive, but, also, negative aspects of patents in pharmaceutical industry. More analytically, the strict policy regarding patents may sometimes be undue, but on the other hand patent system around the world gives always to pharmaceutical industry players a motivation to try harder and to aim at qualitative and innovative products³⁸. Moreover, another interesting aspect of the protection of patents, as intellectual property rights, is that through patent system it is ensured that the proprietor will give the relevant information regarding his patent to the public, whereas someone who has not applied for a patent may keep it confidential.

³³ Atkinson, Jonathan and Rachel Jones "Intellectual property and its role in the pharmaceutical industry" (published 2009) 1547

³⁴ Atkinson, Jonathan and Rachel Jones "Intellectual property and its role in the pharmaceutical industry" (published 2009) 1547

³⁵ Alberto Heimler, "The pharmaceutical industry and parallel trade"

³⁶ Future science, "Intellectual property and its role in the pharmaceutical industry" (published 2009) 1547 available at < <https://www.future-science.com/doi/pdf/10.4155/fmc.09.138>>

³⁷ See Future science, "Intellectual property and its role in the pharmaceutical industry" (published 2009) 1547 available at < <https://www.future-science.com/doi/pdf/10.4155/fmc.09.138>>

³⁸ See Alberto Heimler, "The pharmaceutical industry and parallel trade"

2.4.2. Exhaustion of IPRS

The legal framework of re-importation of goods has to do with the principle of exhaustion of intellectual property rights that is known internationally. It means that when a good with a specific trademark, for example, is sold in a market by the intellectual property right owner, he cannot prohibit the distribution of the good, because there is an exhaustion of his intellectual property rights³⁹. In connection with the above mentioned, in the framework of parallel trade the owner of the intellectual property right may not give his permission in order for the goods to be resold within Members States⁴⁰. However, the procedure is completely lawful in the framework of free movement of goods, because there is an exhaustion of IPRS.

To start with, before analysing the re-importation especially in pharmaceuticals, it has to be examined which is the relationship between exhaustion of intellectual property rights and parallel trade. First of all, it has to be mentioned that all ideas are protected as intellectual property rights⁴¹. For example, an invention is protected as a patent. As a result, if someone is the owner of a patent, he can prohibit the reproduction, sell and distribution for the period of protection, which in most cases is twenty (20) years. The same happens when someone is the owner of a trademark or copyright⁴². As aforementioned, the exhaustion of intellectual property is the basis of the parallel trade. It happens, because, for example, a patent owner cannot control the distribution of a patented good after the sale of the good in the first Member State within the EU internal market with his consent as the proprietor of the intellectual property right. Analytically, depending on the applicable law, there are three ways of exhaustion of intellectual property rights:

- National exhaustion of intellectual property rights that has to do with the exhaustion of the trademark, patent or copyright right on the market that the goods were sold, meaning that parallel importing in the country would lead to

³⁹ See Bart Thomas, "Parallel trade of pharmaceuticals: a review of legal, economic and political aspects", *Value in health*(Volume ii, Number 5, 2008) 996 - 1005

⁴⁰ See Kyle Margaret, "Parallel trade in pharmaceuticals: Firm responses and competition policy" (published 2009), 345

⁴¹ Health Christopher, "Parallel imports and international trade" (published 1997), available at <http://www.wipo.int/mdocsarchives/ATRIP_GVA_99/ATRIP_GVA_99_6_E.pdf>

⁴² See Arfwedson Jacob, "Re-importation (Parallel Trade) in Pharmaceuticals", Institute for Policy Innovation (IPI Center for Technology Freedom, 2004) 5

infringement of the relevant intellectual property right. In this case, intellectual property rights are linked with the country and for this reason, they are limited within the geographical limits of each country. It happens in states, where according to applicable law there is a “principle of national exhaustion”.

- Regional exhaustion of intellectual property rights means that the IPRS are exhausted to a broader market, consisting of different countries.
- International exhaustion of intellectual property rights means that there is an exhaustion of IPRS if the good is launched in any market worldwide. More analytically, in cases where the “principle of international exhaustion” is applied relevant rights are exhausted after the first sale of the good in any market and it means that parallel trade is allowed⁴³.

In any case and according to the above mentioned, what should be taken into consideration is the fact that the main scope of European Union Law provisions is the establishment and functioning of a single EU internal market, according to Articles 34, 35 and 36 of the Treaty on the Functioning of the European Union. As a result, this is why the implementation of the principle of free movement of goods is more important than the exercise of Intellectual Property Rights, meaning that in cases where there is regional exhaustion of Intellectual Property Rights, there is no conflict with the proprietor of the intellectual property rights for the free movement of the goods in European Union. In other words, in the framework of EU single internal market no Intellectual Property Right shall be exercised if it harms or even prohibits the free movement of consumer goods in European Union. However, there is an exemption regarding Article 36 of the Treaty on the Functioning of the European Union which applies in specific and few cases. Depending on the above mentioned, parallel trade started expanding in European Union and EU law cases are trying until today to execute the principle of free movement of goods in any case⁴⁴.

⁴³ See Arfwedson Jacob, “Re-importation (Parallel Trade) in Pharmaceuticals”, Institute for Policy Innovation (IPI Center for Technology Freedom, 2004) 5

⁴⁴ Health Christopher, “Parallel imports and international trade” (published 1997), available at <http://www.wipo.int/mdocsarchives/ATRIP_GVA_99/ATRIP_GVA_99_6_E.pdf>

2.5. Conclusion

To sum up, it is hereby mentioned that parallel trade in consumer goods, in general is something very important for the functioning of the EU internal market European Union. More specifically, last decades a very common phenomenon is parallel trade in pharmaceuticals within Member States, something that has to do, of course, with the existing circumstances in pharmaceutical market in EU. In more detail, the application of Directives and the establishment of European Medicines Evaluation Agency (EMA) were the most important steps for the implementation of the aim of EU Internal Market because, in this way, pharmaceutical companies started following a certain authorization procedure for the whole EU Internal Market⁴⁵. Finally, in this chapter procedure and in this way gain not only time but also money as there is no need to do the same procedure in different countries. Moreover, in this Chapter was mentioned the important meaning of intellectual rights as assets of the companies in pharmaceutical industry, as well as the effects of exhaustion of IPRS.

⁴⁵ See Kyle Margaret, "Parallel trade in pharmaceuticals: Firm responses and competition policy" (published 2009), 345

3. Restraints in Parallel trade of pharmaceuticals and Competition Law

Provisions of EU Competition Law play a vital role in parallel trade in general, its purpose being to ensure the proper functioning of internal market, protecting simultaneously not only the companies, but, also, the consumers of the Member States.⁴⁶

In many cases firms around the world try to prohibit sometimes parallel importing of consumer goods on the basis of certain competition measures. However, in order to examine whether this prohibition is lawful, Articles 101 and 102 of the Treaty on the Functioning of the European Union should be taken into consideration.

3.1. Article 101 TFEU

In more detail, Article 101 TFEU is one of the most important provisions regarding agreements and competition measures in the framework of trade between Member States. The main scope of this Article is the avoidance of “..prevention, restriction or distortion of competition within the internal market..⁴⁷”. It states that there should be no agreements between undertakings affecting trade between Member States and that these agreements are not valid. This Article of TFEU regulates not only many types of agreements between undertakings in Member States, but, also, decisions of undertakings and concerted practices, even without written agreement between them. It is also noteworthy that this Article refers to agreements and practices which “..*have as their object or effect the prevention, restriction or distortion of competition within the internal market..⁴⁸” and in this way it makes distinction between object and effect, meaning that even when there is no object, it should be analysed whether the agreement or practice has similar effects. It, also, mentions in para (3) that there are some exemptions to Article 101 para (1) TFEU, meaning that in some cases the prohibition of Article 101 para (1) shall not be applied, but only under specific circumstances⁴⁹. One of the most important law cases, which will be analysed below, regarding dual pricing system is the GlaxoSmithKline Services Unlimited case,*

⁴⁶ Francesco Liberatore, “Restrictions on parallel trade of pharmaceutical products and EU Competition Law”, Ch 17

⁴⁷ Article 101 (1) TFEU

⁴⁸ Article 101 (1) TFEU

⁴⁹ See Francesco Liberatore, “Restrictions on parallel trade of pharmaceutical products and EU Competition Law”, Ch 17

known as the Spanish GSK case⁵⁰. GlaxoSmithKline, one of the largest pharmaceutical companies in the world, informed the Commission about the system that would adopt regarding the differentiation of its prices in order to get the permission of Commission that in this way there is no infringement of Article 81 of the EC Treaty and that it falls within the exemption occasions of paragraph 3 of the above mentioned Article (Article 101 TFEU now). In more detail, GlaxoSmithKline decided to sell its exported products in higher prices in other Member States, despite the fact that the competent Authorities in Spain had set a specific price for the sale of the products. Of course, the price for the sale of the products of the company in Spain was the one regulated by the Spanish governmental health authorities, but in this way GlaxoSmithKline's practice reduced parallel importing to other countries. In this case, it was decided by Commission that GlaxoSmithKline restricted parallel importing of pharmaceutical products, as it infringed EU Competition Rules and foreign traders from European Union had to pay more for the products of GlaxoSmithKline than the Spanish Authorities have regulated. Further, the Court of first instance (CFI) decided that there was no infringement of EU Competition Law and that there should be examined which was the result by the GlaxoSmithKline's practice, but after CFI's decision, Commission appealed to ECJ. ECJ, finally, decided that dual pricing schemes is a restriction of parallel importing of products by object. However, ECJ decided that Commission should not come to the conclusion that dual pricing system is opposed to Article 81 of the EC Treaty, without taking into consideration that the effects, and examine whether GlaxoSmithKline's practice would give rise to innovation, something very important for the pharmaceutical sector. In this way, ECJ stated that it was very important to be examined whether Article 81 (3) of the EC Treaty (Article 101 (3) TFEU now) could be applied in this case.

3.2. Article 102 TFEU

To continue with, Article 102 TFEU regulates monopolies that affect trade between Member States. Analytically, this Article, which is as important as the previously mentioned (Article 101) has to do with the firms around European Union that have a

⁵⁰ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters) Cases C-501/06, C-213/06, C-515/06 and C-519/06

prevailing position in their sector⁵¹. Thus, as mentioned in Article 102 TFEU, undertakings shall not use their power wrongly, meaning that they shall not use abusive behaviour, unless there are specific justifications, which allow such a behaviour⁵². Otherwise, abusive behaviour as described in the provision of this Article affects the competition, which is specifically regulated in EU Law provisions. Regarding Article 102 TFEU, there is an important law case, which will be analysed more in the next chapter and refers to the system of allocation. This case is known as *Sot Lelos kai Sia EE v GlaxoSmithKline A EVE (GSK A EVE)*⁵³ and has to do with GSK A EVE, which suddenly, in 2000, started selling its medicinal products mainly to Greek hospitals and pharmacies and as a result, there was not enough quantity of products to be sold to Greek wholesalers as well. ECJ decided that every undertaking is lawfully able to take measures in order to secure its own interests in the framework of its own trade performance, but only if there is no aim of abusive behaviour because of a dominant position. Moreover, the Court of Justice claimed that what should be taken into account in order to examine whether there is an abuse or not in cases of allocation systems, is whether a wholesaler was always ordering the same quantity of products by the supplier and also if the quantity asked by the wholesaler is big enough in comparison with the general interests of the specific area of trade and as ECJ stated, this is an issue that should be decided by the local courts. In any case, ECJ mentioned that the claim of GSK A EVE that this practice is in favour of consumers is not acceptable and decided finally, that this practice is beneficiary for both parties.

3.3. Conclusion

To sum up, it has to be mentioned in this chapter that Competition Law provisions play a major role in parallel trade among Member States and help the functioning of EU Internal Market. However, there are many cases according to which companies, despite the principle of free movement of goods, try to prohibit the parallel trade of products between companies in European Union depending on Competition Law

⁵¹ Gotz Drauz "The pharmaceutical sector and competition law in Europe", (published at MULTI-INDUSTRY) available at <<https://www.wsgr.com/publications/PDFSearch/drauz-0312.pdf>>

⁵² Article 102 TFEU

⁵³ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters) Cases C-468/06 to C-478/06

measures of Articles 101 and 102 of the Treaty on the Functioning of the European Union, the legality of which should be examined from time to time.

4. Parallel trade law cases

As analyzed in this paper, parallel trade in pharmaceuticals is a very common phenomenon among Member States nowadays. The main reason why parallel trade is so popular in pharmaceutical sector and more specifically, in pharmaceutical companies around EU, is that companies can re-sell pharmaceutical products in higher prices, even if they bought them in Member States that due to national regulations have lower prices. In this way, traders make extremely high profits according to the European Law and the principle of free movement of goods. However, there are many unclear issues regarding to which there is considerable volume of Court of Justice case law. For example, there are many law-cases regarding the compliance of trade methods with EU Competition Law rules and especially with Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU). Analytically, some of the most important issues are dual pricing schemes and supply allocation systems in the framework of trade of pharmaceutical products. Finally, another very important issue regarding parallel trade in pharmaceutical sector, is repackaging of pharmaceutical products, which has raised many disputes and as a result, there are many decisions trying to interpret related regulations⁵⁴.

4.1. Dual pricing system

To start with, dual pricing system is a method which pharmaceutical firms around European Union use because of the parallel trade which takes place in this sector. It means that EU pharmaceutical firms have two (2) different prices for their medicinal products in relation to the country that they sell the products. One for the domestic market and one for the foreign countries, meaning a higher price for the other EU countries. It has been examined whether dual pricing schemes is a system that restricts competition between EU Member States on the basis of Article 101 TFEU.

4.1.1. GlaxoSmithKline Services Unlimited Case

⁵⁴ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters)

One of the most important law cases regarding dual pricing system is the GlaxoSmithKline Services Unlimited case⁵⁵, as above mentioned, known as the Spanish GSK case. GlaxoSmithKline, one of the largest pharmaceutical companies in the world, informed the Commission about the system that would adopt regarding the differentiation of its prices in order to get the permission of Commission that in this way there is no infringement of Article 81 of the EC Treaty and that it falls within the exemption occasions of paragraph 3 of the above mentioned Article (Article 101 TFEU now). In more detail, GlaxoSmithKline decided to sell its exported products in higher prices in other Member States, despite the fact that the competent Authorities in Spain had set a specific price for the sale of the products. Of course, the price for the sale of the products of the company in Spain was the one regulated by the Spanish governmental health authorities, but in this way GlaxoSmithKline's practice reduced parallel importing to other countries.

In this case, it was decided by Commission that GlaxoSmithKline restricted parallel importing of pharmaceutical products, as it infringed EU Competition Rules and foreign traders from European Union had to pay more for the products of GlaxoSmithKline than the Spanish Authorities have regulated. Further, the Court of first instance (CFI) decided that there was no infringement of EU Competition Law and that there should be examined which was the result by the GlaxoSmithKline's practice, but after CFI's decision, Commission appealed to ECJ. ECJ, finally, decided that dual pricing schemes is a restriction of parallel importing of products by object. However, ECJ decided that Commission should not come to the conclusion that dual pricing system is opposed to Article 81 of the EC Treaty, without taking into consideration that the effects, and examine whether GlaxoSmithKline's practice would give rise to innovation, something very important for the pharmaceutical sector. In this way, ECJ stated that it was very important to be examined whether Article 81 (3) of the EC Treaty (Article 101 (3) TFEU now) could be applied in this case.

⁵⁵ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters) reference to Cases C-501/06, C-213/06, C-515/06 and C-519/06

4.2. Supply quota system

The supply quota system has to do with the fact that sometimes suppliers minimize the supply of goods and supply products only for domestic needs and not for parallel trade.

4.2.1. Bayer/Adalat case

Another very important case, in the framework of parallel trade in pharmaceuticals is Bayer/Adalat case⁵⁶. To analyse it, this is a case regarding an undertaking that refused to supply its product, but this company - on the contrary of the previously mentioned case - was not in a dominant position. Adalat is a medicinal product produced by Bayer, which is sold in many Member States in a certain price, which local authorities have regulated every time. Between 1989 and 1993 the drug, French and Spanish authorities decided that the price of Adalat would be lower. As a result, and because of the fact that in UK this drug was almost 40% more expensive, traders from Spain and France decided to export it to UK and in this way, the sales of the product by the subsidiary company of Bayer established in UK were extremely reduced. For this reason, Bayer stopped selling so large quantities to wholesalers from Spain and France, leading to the decision of Commission that Bayer behaved on the contrary of the provisions of Article 101 TFEU. Despite Commission's decision, CFI mentioned that there was no agreement between Bayer and the wholesalers. ECJ agreed with CFI, a very important decision which means that, in general, suppliers of pharmaceutical products with no dominant position, have the ability to prevent parallel export of goods if there is no agreement between them and the wholesalers.

4.3. Supply allocation system

Another important issue concerning parallel trade in pharmaceuticals, is the system of allocation, meaning that sometimes companies limit the quantities of supply of their products in order to reassure that there should be enough quantities on the basis of the commercial interests of every undertaking.

⁵⁶ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters) reference to Cases T-41/96 and C-02/01

4.3.1. Sot Lelos kai Sia EE v GlaxoSmithKline AEVE (GSK AEVE)

Regarding allocation systems, there is a worldwide known case Sot Lelos kai Sia EE v GlaxoSmithKline AEVE (GSK AEVE)⁵⁷. In this famous case, GSK AEVE, which was a subsidiary company of GlaxoSmithKline in Greece, for many years supplied many wholesalers in Greece. Afterwards, wholesalers were selling these pharmaceutical products not only in Greece, but, also, in other Member States where the prices were higher. Suddenly, in 2000, GSK AEVE started selling its medicinal products mainly to Greek hospitals and pharmacies and as a result, there was not enough quantity of products to be sold to Greek wholesalers as well. On the basis of the above mentioned practice GSK AEVE, started a legal dispute by Greek wholesalers in front of the Greek Courts, claiming that GSK AEVE infringed Article 82 of the EC Treaty (Article 102 TFEU now) in an abusive manner, because of its dominant position. The Court of Appeals in Greece, noticed ECJ and asked for a preliminary ruling with regards to the practice of GSK AEVE and whether this company was able according to the EU Law to reduce the supply of its products, in order to stop Greek wholesalers from exporting them to other Member States and gaining profit. ECJ decided that every undertaking is lawfully able to take measures in order to secure its own interests in the framework of its own trade performance, but only if there is no aim of abusive behaviour because of a dominant position. Moreover, the Court of Justice claimed that what should be taken into account in order to examine whether there is an abuse or not in cases of allocation systems, is whether a wholesaler was always ordering the same quantity of products by the supplier and also if the quantity asked by the wholesaler is big enough in comparison with the general interests of the specific area of trade and as ECJ stated, this is an issue that should be decided by the local courts. In any case, ECJ mentioned that the claim of GSK AEVE that this practice is in favour of consumers is not acceptable and decided finally, that this practice is beneficiary for both parties.

⁵⁷ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters) Cases C-468/06 to C-478/06

4.4. Repackaging procedure

Finally, one of the most important issues in parallel trade of pharmaceuticals, not only in European Union, but, also, all over the world is the repackaging of goods which has to do with the exhaustion of intellectual property rights⁵⁸.

4.4.1. Bristol-Myers Squibb case

For example, in one of the most known cases, Bristol-Myers Squibb case⁵⁹, ECJ stated that there are some specific criteria which should be examined in order to decide whether a repackaging procedure is lawful. First of all, the repackaging process should take place only if it is obligatory for a certain reason and in any circumstances, the name of the company that did the procedure should be placed upon the package together with the supplier. Moreover, repackaging shall not damage the product and undoubtedly, the intellectual property owner, meaning the trademark owner, who should be informed for the repackaging process. On the contrary, ECJ mentioned in another very important case, Orifarm and Paranova v Merck Sharp and Dohme⁶⁰, that according to EU Directive and trademark regulations⁶¹, a trademark owner cannot prevent the sale of a good after repackaging, because it is not possible to refer the company, that did the repackaging procedure, upon the new package.

4.5. Conclusion

Finally, from the above mentioned it is without doubt that the framework of parallel trade in pharmaceuticals will remain uncertain, until all law cases have the same conclusion. As we can see companies around European Union do not follow strictly the principles of European Union, meaning that the cases examined by ECJ are even more.

⁵⁸ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters)

⁵⁹ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters) reference to joint cases C 427/93, C-429/93 and C-436/93

⁶⁰ Christophe Henim, "Parallel trade and pharmaceuticals in the EU: current issues", (published 2018, Thomson Reuters) reference to joint cases C-400/09 and C-207/10

⁶¹ Article 7 (2) of the Trademarks Directive 2008/95/EC

5. Review of the parallel importing in pharmaceuticals

Undoubtedly, parallel trade in pharmaceuticals is a phenomenon with not only positive, but, also, negative aspects. In this chapter will be analysed the impact of parallel trade on pharmaceutical sector and will be made a prediction about the future of parallel trade in the future.

5.1. Positive and negative aspects of parallel trade in pharmaceuticals

5.1.1. Positive aspects

Parallel trade in pharmaceuticals, which is based on the basic principle of European Union for the free movement of goods, has, undoubtedly, many advantages.

To start with, parallel trade gives to the patients the opportunity to buy the essential for their health drugs in lower price⁶². For this reason, consumers, many times prefer to buy a drug which is parallel imported and in lower price sold, than a drug supplied in their own country, which is more expensive, according to the regulations of the local health authorities. Cheaper pharmaceutical products means, further, that the cost of the health insurance authorities of the Member States is lower, as they give less money for the reimbursement of the pharmaceutical products, which consumers buy. As a result, health insurance authorities of the countries gain savings, something very important for them⁶³.

Another, very important positive aspect of parallel trade of pharmaceutical products is the fact that it contributes to the creation and development of the internal EU Market, which should be a responsible and competitive environment. It means, that free movement of pharmaceutical products in Member States ensures an environment conducive to intra-brand competition that gives not only to the consumers, but, also, to the traders the opportunity to select which is the best and more economically advantageous solution to their commercial needs and interests.

⁶² European Association of Euro-Pharmaceutical Companies, "What are the benefits?", available at <<http://www.eaepc.org/parallel-distribution/who-gains/benefits>>

⁶³ Claudia Desogus, "Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel trade" (published 2013) ch 1, 39-42

Finally, from a financial point of view, parallel trade in pharmaceuticals is a very economically profitable way for the countries of the manufacturers of medicinal products, as they earn foreign exchange through transactions with foreign countries. Moreover, in the framework of these transactions between Member States, there is a great need for new work positions around European Union, because parallel trade is a new field for traders and in order to be successful in the whole EU internal market, pharmaceutical companies should appoint experienced staff with financial and legal knowledge to this positions.

5.1.2. Negative aspects

Despite to the above mentioned, parallel trade in pharmaceuticals has many disadvantages as well that have to be examined by the competent authorities.

Firstly, it is undeniable fact that parallel trade in pharmaceuticals is not of great advantage for the consumers around European Union. In more detail, consumers do not gain directly money, as in all countries the highest proportion of the cost of medicines is undertaken by the health security system of each country, which at last gain the savings. As a result, it is without doubt that parallel importers have more benefits by this situation.

To continue with, another problem due to parallel trade in pharmaceuticals is that sometimes manufacturers do not have enough quantity of products in order to supply not only foreign countries, but, also the domestic market, meaning consumers, pharmacies and hospitals.

Moreover, it has to be mentioned that pharmaceutical companies have to examine which should be the price in every country that they do business and especially parallel importing of drugs. Consumers cannot afford the same prices in every country and this is why price discrimination is a very important issue in parallel trade. A solution could be that a specific drug has the same price in every country, but this is something that could create problems and inequality and for this reason, it has to be examined every time⁶⁴.

⁶⁴ Claudia Desogus, "Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel trade" (published 2013) ch 1, 39-42

Finally, one very important negative aspect of parallel trade in pharmaceuticals is that because of it, pharmaceutical companies face many times profit losses. Furthermore, because of that, motivations for innovation become even fewer, because as it is known, pharmaceutical industry depends on Research and Development (R&D), something which means that pharmaceutical firms shall spend not only money, but also a long period in order to develop qualitative new pharmaceutical products. However, pharmaceutical companies do not invest much money in new drugs, as they do not have enough profits and following that they manufacture and sell cheaper products of poor quality⁶⁵.

5.2. Parallel trade of pharmaceuticals in the future

It is without doubt, that next years parallel trade in pharmaceuticals should remain a very crucial issue not only for pharmaceutical companies or consumers, but, also for the whole European Union. Especially, nowadays, in the midst of global economic crisis, with strong impact on the economy of the most Member States, parallel trade of pharmaceuticals gives many choices regarding the purchase of drugs. Besides, as it can be observed within the recent few years there have been a significant effort for the developing of a more specific legal and financial framework of parallel trade in pharmaceuticals through agreements between Member States and also, through case law that make more clear which are the criteria for the establishment of lawful parallel importing of consumer goods, and more specifically of pharmaceutical drugs.

5.3. Conclusion

From the above mentioned, it has to be stated that parallel trade in pharmaceuticals has not only advantages but also disadvantages for the whole European Union. Undoubtedly, the fact that patients can buy from a wide range of products in higher or lower prices is something important. However, the main advantage has to do with the health security systems that gain money, as in any case the patient pays only a small

⁶⁵ Bart Thomas, "Parallel trade of pharmaceuticals: a review of legal, economic and political aspects", *Value in health*(Volume ii, Number 5, 2008) 1000

amount when buying a pharmaceutical product. Another very important positive aspect of parallel trade of pharmaceutical products is the fact that it contributes to the development of the internal EU Market. Parallel trade in pharmaceuticals has many disadvantages as well, such as the fact that consumers do not make such savings as health systems do and that producers sometimes do not have enough quantity of products. It remains to be seen which will be the circumstances in parallel trade of pharmaceuticals in some years

Conclusions

It is without doubt that parallel trade in pharmaceuticals in European Union plays a vital role in the pharmaceutical sector. Parallel trade in general, and specifically, of pharmaceutical products is based on the general principle of the free movement of goods between Member States according to Articles 34, 35 and 36 TFEU. In any case, when parallel trade in pharmaceuticals is examined, as above stated, not only Intellectual Property Law provisions, but, also, Competition Law provisions should be taken into consideration.

On the one hand, as analysed in this paper, parallel trade in pharmaceuticals has some positive aspects, meaning, for example, that consumers sometimes buy pharmaceutical products in lower prices or that governmental health authorities can have savings because of parallel trade. Moreover, parallel trade helps the function of internal market in European Union and ensure a competitive environment between Member States. However, on the other hand it is clear that the most positive effects of parallel trade in pharmaceuticals have to do with the parallel traders and not with the consumers or the Member States.

All these years, as we can easily understand, ECJ is trying to find the best way in order to level out the benefits of parallel importers, consumers and pharmaceutical companies. However, it has been proven that this is not an easy procedure. For example, there are many people saying that pharmaceutical companies sometimes have a negative effect from parallel trade in pharmaceuticals and as a result they do not invest in new drugs, but prefer to take money even for the most low-quality new drug.

At this point, it should be mentioned which is the role of Competition Law provisions in parallel trade in pharmaceuticals. The law cases until today prove, more specifically, that Article 101 TFEU gives to pharmaceutical companies the opportunity to put restrictions in cross-border trade between EU Member States depending on Article 101 (3) TFEU that states some exemptions in the general principle of EU Law about prohibition of agreements between parties that in any way try to restrict competition between Member States. For sure, in the nearest future, pharmaceutical companies will most frequently try to put obstacles in parallel importing due to financial crisis, trying in this way to avoid loss.

To sum up, in my opinion, according not only to the general circumstances and changes in pharmaceutical market in EU, but, also, to the law cases and decisions of ECJ, there is a general understanding of the problems of pharmaceutical companies around European Union, but it should be balanced with the principle of free movement of goods in European Union. However, it is true that competent authorities understand the concerns of pharmaceutical firms that face negative effects and financial problems because of the fact that through parallel importing other companies gain money despite the fact that they may have not spent money or time on Research and Development procedures. The ideal scenario would be if there was a mechanism and the respective regulations that could protect the commercial interests of pharmaceutical companies without restricting parallel trade between Member States. Pharmaceutical companies could also lead to this direction by trying to find solutions according to which parallel trade and competition between Member States will not create problems to the commercial interests of pharmaceutical companies. For example, if they try to promote all the innovative drugs which they produce, they will give ground to competition between Member States and protect their commercial interests.

In any case, the interests of patients should be always be more important than the interest of pharmaceutical companies and as result the patient protection and the principle of free circulation of goods should be the criteria for parallel trade between Member States in the future.

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