FACULTY OF LAW
Stockholm University

Parallel Trade of Pharmaceutical Drugs Within the European Union
- A Competition Law Perspective

Natasha Abedi Valugerdi

Thesis in *European Union Law , 30* HE credits
Examiner: *Björn Lundqvist*
Stockholm, *Autumn* term 20*17*

Stockholm University

Table of Contents

List of abbreviations

CFI	Court of First Instance
EC Treaty	European Community treaty
ECJ	European Court of Justice
EEA	European Economic Area
EEC	European Economic Community
EFTA	European Free Trade Association
EPC	European Patent Convention
EU	European Union
GSK	GlaxoSmithKline
TEU	Treaty of the European Union
TFEU	Treaty on the Functioning of the European Union

Definition of Terms

Member State of destination: is the Member State where a product is intended to be imported.

Summary

Parallel trade occurs when a product covered by intellectual property rights is purchased at a low price in one country and imported to another country at a higher price. This conduct results in a profit for the parallel importer. Under EU law this kind of business is permitted. One of the fundamental objectives of the EU is to create a single market where goods, services, capital and people can move freely between the Member States. Article 34 of the TFEU states that any quantitative restriction or measure with equivalent effect that causes a hindrance to trade is prohibited. Furthermore, the ECJ has clarified the legality of parallel trade by establishing the principle of exhaustion. The principle of exhaustion implies that once a product has been placed in the European market by the proprietor or with his consent, the proprietor may not prevent others from further selling or distributing said product by claiming infringement of intellectual property rights. Unfortunately, this highly valued principle has become a problem for owners of intellectual property rights. One sector that is greatly affected by parallel trade, is the pharmaceutical sector and the manufacturers of medicinal products. The pharmaceutical sector is an intriguing sector, as the prices of the products are usually set by the governments of the Member States. Member States have a responsibility to ensure that pharmaceutical drugs are provided, available, and affordable. However, this puts pharmaceutical drug manufacturers in a tough spot, as they cannot control the prices of the products, and they cannot prevent parallel traders from selling products cheaper. In recent years, pharmaceutical companies have tried to prevent parallel trade by using different competitive measures. However, the question remains whether these competitive measures are permitted under Article 101 TFEU and 102 TFEU. This paper will explore what measure pharmaceutical companies can take to prevent parallel trade without breaching the competition rules laid out in Article 101 TFEU and 102 TFEU.

1. Introduction

1.1 Background

The establishment and functioning of an internal[1] European Market has been one of the most central aspects of the European Union (EU) since the dawn of its existence in 1957.[2] The notion of a European single market is characterized by the abolishment of obstacles to the free movement of goods, services, persons, and capital.[3] This means that there should be no hindrance to trade within the EU. As a means of achieving and maintaining this objective, EU law aims to support and protect parallel trade. [4] Parallel trade is the cross-border sale of products by independent companies, outside the manufacturers distribution system without the consent of the manufacturer. These companies generate profit by purchasing products from one Member State at a low price, then selling the product at a higher price in another Member State.[5] Parallel trade increases consumer welfare, as imported products from a Member State with lower prices, forces sellers in the Member State of destination to reduce their prices.[6]

A field of law where parallel trade plays a prominent yet controversial role, is the pharmaceutical sector.[7] Since the pharmaceutical sector is partially regulated by the states, especially when it comes to costs, price differentials in pharmaceutical drugs occur between the Member States. The varying prices of medicinal products can generate great profit and make parallel trade a lucrative business for parallel traders or wholesalers.[8] However, in many cases the original makers of these pharmaceutical drugs try to hinder parallel trade by entering agreements or engaging in unilateral conduct in order to prevent the reduction of their profits. These practices can be highly risky and the question arises whether these restrictions violate Article 101 of

[1] Also known as the Single European Market
[2] Bernitz U, and Kjellgren A. *Europarättens grunder*. 5th Ed. Norstedts juridik, Stockholm 2014. p. 264
[3] Barnard C, *The substantive law of the EU: the four freedoms*, 5 ed., Oxford University Press, Oxford, 2016 p. 10
[4] Neruda R, Barinka R Minárik M, *Parallel Imports in EU Law,* published in Lexology, 2015 p.1
[5] Regarding this section see further, Pat Treacy K, Watson-Doig N, *What is Parallel Trade and How Does it Affect Pharma ?* Knect 365 Law, CompLaw Blog, 2016.
[6] Neruda R, Barinka R Minárik M, p.1-2
[7] Neruda R, Barinka R Minárik M, p.1-2
[8] Ibid

the Treaty of the Functioning of the European Union (TFEU) which imposes a general ban on agreements that distort competition, or Article 102 TFEU which prevents the abuse of dominant position.[9] This paper will aim to discuss this highly controversial area of competition law and parallel trade.

1.2 Aim

The purpose of this paper is to examine the relevant EU competition rules regarding parallel trade of pharmaceutical drugs and its effect on pharmaceutical companies. In doing so, the following questions will be answered:

What are the possible consequences of parallel trade of pharmaceutical drugs within the EU? How can pharmaceutical companies prevent parallel trade of pharmaceutical drugs within the EU without breaching Article 101 TFEU? When is the refusal of a dominant pharmaceutical drug manufacturer to supply orders, considered abusive under Article 102 TFEU?

1.3 Method and Material

The sources of law that have been used in this paper, are EU legislation and case-law from the European Court of Justice (hereinafter ECJ). The legislative texts include both primary and secondary law. However, since the EU legislative texts and ECJ's decisions are sometimes rather vague, doctrine has been used to facilitate the understanding and meaning of the texts and the decisions. Furthermore, opinions from the General Advocate and notices from the Commission have been used to further explain the aims and objectives of the EU.

Since the aim of this paper is to analyze the legislation regarding parallel importation of pharmaceutical drugs, the EU legal method has been used. The EU legal method is based on the methods of interpretation recognized by the ECJ. These include inter alia the lexical, systematic, teleological and historical method of interpretation. The ECJ is known for using various methods of interpretation in its practice, however this paper has focused on the lexical, systematic and teleological methods of interpretation. It follows from Article 19 TEU, that the ECJ must ensure that in its interpretation and application of the Treaties the law is observed. [10] In other words, the ECJ must make sure that the rule of law is observed. When it comes to the Treaties, the Vienna

[9] Regarding this section see, Neruda R, Barinka R Minárik M, p.2
[10] See Article 19 TEU

Convention on the Law of the Treaties[11], establish that these three methods are to be used when interpreting the Treaties.[12] However, the ECJ has also recognized and applied these methods when interpreting secondary legislation.[13]

The lexical method of interpretation aims at explaining the meaning of normative texts by examining the usual definition of the words. This method is often used by the ECJ to restrict a wide interpretation of a certain provision and guarantee legal certainty. [14] The systematic interpretation focuses on the EU legal order as a system. This method of interpretation assumes that the authors of the Treaties have established a complete and consistent legal order and EU legislators and Judges shall act in accordance with this principle.[15] Article 7 of the TFEU, expressly states that the EU shall ensure consistency in all its policies and activities. The aim of this method is to establish consistency and coherency in the EU s policies and function, taking into account its objectives. The teleological method focuses on the objective and purpose of the EU and its policies. The ECJ has often given priority to this method when interpreting primary law. This comes as no surprise as the Treaties contain essential objectives of constitutional importance that the EU must attain. Furthermore, this method of interpretation is used by the ECJ to give meaning to general provisions and to fill in the gaps between precise and complex secondary law, and vague general primary law.[16]

1.4 Delimitation

The primary aim of this paper is to analyze the issues that arise with parallel trade of pharmaceutical drugs within the EU from a competitive law perspective. Consequently, issues that are related to intellectual property rights will only be discussed to the extent they are relevant to the paper and necessary to answer the questions stated above. In this regard, it is also important to note that focus will be mostly on patent and trade mark rights as these intellectual property rights are the

[11] United Nations, *Vienna Convention on the Law of Treaties*, 23 May 1969, United Nations, Treaty Series, vol. 1155, p. 331(hereinafter Vienna Convention)
[12] See Article 31 and 32 Vienna Convention
[13] See Judgement of the Court of 15 October, Annette Henke v Gemeinde Schierke and Verwaltungsgemeinschaft Brocken, Case C-298/94, ECLI:EU:C:1996:382
[14] See further Lenaerts K, Gutiérrez Fons J, *To Say What the Law of the EU is: Methods of Interpreation and the European Court of Justice*, EUI Working Papers AEL2013/9 Academy of European Law Distinguished Lectures of the Academy. 2013, p. 6-7
[15] See further regarding this method Lenaerts K, Gutiérrez Fons J, p. 13-14
[16] Regarding this method see further Lenaerts K, Gutiérrez Fons J, p. 24-25

most common rights associated with pharmaceutical drugs. Although parallel trade is greatly related to free movement of goods, Articles 34-36 TFEU will only be mentioned in so far it is necessary to understand the main objectives of the EU. Furthermore, this paper will solely focus on parallel importation within the EU, thus, parallel import of goods outside the EU will only be mentioned to the extent it is necessary to understand the legal background.

Lastly, this paper only deals with the "refusal to supply"[17] method that pharmaceutical companies have adopted to prevent parallel trade. In other words, refusal to license falls outside the scope of this paper. Another problem that pharmaceutical companies face is the generic entry of pharmaceutical drugs. Recently controversial cases that deal with patent strategies to prevent generic entry have been used by pharmaceutical companies to prevent the importation of these products into the market. Although these cases serve as interesting discussion points they will not be discussed to a great extend in this paper.

1.5 Outline

This paper will be divided into six main chapters. The paper will begin by presenting the legal framework relevant for this research paper in chapter two. This chapter will not only present the EU's constitutional law, it will also provide a short description of the norm-hierarchy of the EU. Since parallel trade is a complicated business that affects several areas of law chapter two will also present the relevant legal background concerning the internal market, intellectual property law and competition law. This outline is meant to give the reader an understanding of how parallel trade affects these three areas of law and how these three areas of law interact with one another. This chapter also aims to highlight the objectives the EU is striving to reach. Chapter three will explain the concept of parallel trade and what role this phenomenon plays in the pharmaceutical sector. Furthermore this chapter will aim to present relevant secondary legislation in the field of intellectual property rights to facilitate the understanding of parallel trade and exhaustion principle with a special focus on trade marks. Chapter three will also discuss the relationship between intellectual property law and competition law. Chapter four will introduce the various competitive measures pharmaceutical companies have adopted in order to restrict

[17] This method of limiting parallel trade will be discussed further below.

parallel trade. This chapter will mostly present case law from the ECJ. Chapter five will present an analysis of the case law from the EU, and provide a discussion on the effects of parallel trade. Chapter five will also discuss solutions to the problems that arise with parallel trade and discuss answers to the research questions stated above. The paper will end with a summary as well as a final conclusion.

2. EU's Structure and Legal Framework

2.1 EU's Constitutional Law

EU law is derived from various sources of law. The three main sources relevant to this paper are primary law and secondary law, including case law from the ECJ. The EU treaties that are the result of negotiations between the Member States make up EU's primary law. These Treaties set out the most fundamental features and functions of the EU, and are equivalent to constitutional law at national level.[18] The Treaties include the Treaty on the European Union[19] (TEU) and the Treaty on the Functioning of the European Union[20] (TFEU). Article 6 in the TEU states that the Charter of the Fundamental Rights of the European Union[21] (EU Charter) has the same legal value as the Treaties. Primary law and the EU Charter are binding sources of law, and consequently Member States must abide by them.

The Treaties only serve as a legal framework and give rise to the main principles of the norm system in the EU. It is however secondary law that specifies the legal rules that Member States must follow. Secondary law is comprised primarily of regulations, directives and decisions.[22] Directives must be implemented into national law by the Member States within a certain time period. In other words, directives are not directly applicable and they do not have direct effect.[23]Individuals can not invoke provisions of the directives in their dealings with public authorities or national courts.[24]

[18] Regarding this section see, Shorthose S, Smillie M, *Overview of European Pharmaceutical Regulatory Requirements, Guide to EU Pharmaceutical Regulatory Law*, 2010 Kluwer Law International, p. 26
[19] Consolidated Version of the Treaty on European Union, 2012 O.J. C 326/13.
[20] Consolidated Version of the Treaty on the Functioning of the European Union, 2012 O.J. C 326/47.
[21] Charter of Fundamental Rights of the European Union, 2012 O.J. C 326/391.
[22] Bernitz U, Kjellgren A, p. 54
[23] See Article 288TFEU
[24] However, if directives are not transposed into national law within a certain time period, and they are sufficiently clear, precise, and unambiguous, the directive can have direct effect. See

Regulations on the other hand become binding national law as soon as they are passed. They require no form of implementation, and consequently they have direct effect. [25]

Regulations and Treaty provisions can confer rights on private individuals, as well as impose obligations on them. Directives, on the other hand, can only confer rights on individuals against the state. They do not confer rights on individuals against other individuals.[26] In other words directives only have "vertical direct effect". Regulations and Treaty provisions are capable of having horizontal direct effect as well as vertical direct effect.[27]

2.1.1 Competence

Under Article 5 TEU, the limits of the EU's competences are governed by the principle of conferral. The principle of conferral implies that the EU shall act within the limits conferred upon it by the Member States to attain the objectives set out therein. Competence that has not been conferred to the EU remains with the Member States.[28] Article 3 (1) TFEU lists a number of areas in which the EU has exclusive competence such as the customs union and the common commercial policy.[29] In these areas only the EU may legislate and adopt legally binding acts.[30] However, the EU shares competence with the Member States in other areas, like the internal market.[31] This means that both the EU and the Member States may regulate the area, but, the Member States may only exercise their competence to the extent the EU has not exercised its powers.[32]

---

futher, Fact Sheet on the European Union 2017, Sources and Scope of European Union Law, p. 3

[25] Shorthose S, Smillie M, p. 27

[26] There is however an exception, directives can give horizontal direct effect to specific provisions in the EU Charter; See Judgment of the Court of 19 January 2010 Seda Kücükdeveci v Swedex GmbH & Co. KG, Case C-555/07, ECLI:EU:C:2010:21

[27] Regarding this paragraph see Hartley TC, The Foundations of European Union Law, Oxford University Press, 7th ed. 2010, p. 224, Treaty and regulation provisions must be clear, unambiguos, unconditional, and not dependent on further action by the Union to have direct effect.

[28] See Article 5 TEU

[29] See Article 3 (1) TFEU

[30] See Article 2(2) TFEU

[31] See Article 3 (2) TFEU

[32] See Article 2 (2) TFEU

2.1.2 Harmonization Within the EU

The interpretation of the Treaties has served as an important tool to achieve market integration within the EU. However secondary legislation has become a more common way to aid the process of bringing Europe together.[33] The EU may adopt legally binding acts such as regulations introducing EU rules, or directives approximating national laws also known as harmonization.[34] Harmonization means that if a situation falls within the ambit of a relevant directive the Treaty provisions are not applicable. Instead Member States are obliged to interpret their national provisions in the light of the directive.[35] This is of course the case when the EU measure fully harmonizes the area. If the measure only partially harmonizes the area, the un-harmonized area can still be subject to scrutiny under primary law.[36]

2.1.3 Legal Basis

By setting harmonized standards EU law enables goods persons services and capital to move freely within the EU.[37] However, under the principle of conferral[38], a legal basis must be established in order to adopt a directive. Article 114 TFEU sets out the legal basis for adopting directives. The said Article states that the European Parliament and Council shall, adopt measures for the approximation of laws, which have as their object the establishment and functioning of the internal market. Article 114 TFEU sets the legal ground for harmonizing the internal market.[39]

EU's subsidiary competence is stated in Article 352 TFEU and it is on the basis of this legal ground that regulations are adopted.[40] Article 352 TFEU gives the EU the power to exercise its competence in areas where such powers have not been explicitly

[33] Regarding this section see Granmar C, *Intellectual property rights and the single market*, European Intelletual Property Law, Rósen j, Edward, Elgar Publishing Limited, 2016, Ch. 2, p. 43
[34] Granmar C, p. 43
[35] Regaridng this section see: Europeiska kommissionen. Generaldirektoratet för näringsliv, *Fri rörlighet för varor: handledning för tillämpningen av fördragets bestämmelser om fri rörlighet för varor*, Europeiska unionens publikationsbyrå, Luxemburg, 2010. p. 9
[36] Barnard C, p. 36
[37] Barnard C, p. 559
[38] See Article 5 TEU
[39] See further Barnard C, p. 559
[40] Granmar C, p. 45

stated in the Treaties in order to attain an objective of the Treaties.[41] It must be observed that unanimity is required to adopt a regulation.[42]

2.2 EU's Internal Market

2.2.1 Free Movement of Goods

One of the most central parts of the EU, is the establishment and function of the internal market.[43] Primary law provides various provisions regarding how the internal market should function and what measures are needed to ensure its establishment and function.[44] One of the essential objectives of the internal market is the removal of trade barriers between Member States and the establishment of free movement within the whole EU. The free movement of goods, services, persons and capital are known as the four freedoms and constitute one of the fundamental rights within the EU.[45]

Kommenterad [GV1]: rewrite

2.2.2 Article 34 TFEU

Due to the EU's aim to move towards a single market and eliminate trade barriers, parallel trade is permitted within the EU. Articles 34-35 TFEU set the legal basis for banning actions that prevent the free movement of goods between Member States.[46] Article 34 TFEU provides that, quantitative restrictions and measures having equivalent effect are prohibited between Member States. A central principle has been that Members States are prohibited from discriminating or preventing products of other Member States from being imported, by having for example special quotas, importation clauses, or demanding certain import licenses.[47] As well as this, Article 34 TFEU also prevents measures having equivalent effect to quantitative restrictions. Measures having equivalent effect concerns other barriers to trade, such as national rules on packaging and labelling. However, the wording of Article 34 TFEU is rather vague as it does not specify what is meant by measures having equivalent effect. [48] As a result, this controversial and vague phrase has given rise to a wide range of case law

[41] See Article 352 TFEU
[42] Article 352 TFEU
[43] Bernitz U, Kjellgren A, p. 264
[44] See Article 3(3) TEU and Article 26 TFEU
[45] Regarding this section see, Bernitz U, Kjellgren A, p. 266, See also Article 26 TFEU
[46] Kyle M, Parallel trade in Pharmaceuticals: Firm Responses and Competition Policy, Fordham Competition Law Institute, 2009, Chapter 13, p. 341
[47] Likewise, Article 35 TFEU prohibits quantitative restrictions on exports. However, as restricting imports from other Member States are usually more problematic, Article 35 is less relevant in this setting.
[48] Regarding this section see Barnard p. 36.

from the ECJ. In the famous *Dassonville*[49] *case* the ECJ shed some light on the meaning of this phrase. The ECJ stated that measures having equivalent effect are measures adopted by the Member States that can constitute a barrier, directly or indirectly, actually or potentially to trade within the EU. This implies that the size of the barrier and whether the measure actually constitutes a barrier is irrelevant.[50]

2.2.3 Article 36 TFEU

There are a few exceptions to the principle of free movement of goods. Both Articles 34-35 TFEU are subject to derogations stated in Article 36 TFEU. Article 36 TFEU provides derogations based on grounds such as public policy, public health, public security, protection of life and so forth.[51] Article 36 TFEU is most commonly used by Member States to prevent the import of goods that threaten the national production. As a result, the ECJ has adopted a narrow interpretation of the derogations provided in Article 36 TFEU. Even if the ECJ recognizes that a public interest is at stake, any action taken by a Member State must still be deemed appropriate.[52]

Furthermore, in the *Cassis de Dijon*[53] case the ECJ developed a vague category of mandatory requirements, such as public health or consumer protection as justified barriers to trade, given that they are proportionate.[54] The ECJ adopted these requirements as a supplement to the derogations mentioned in Article 36 TFEU and has since then recognized a range of other mandatory requirements such as protection of the environment and national socio-cultural characteristics.[55] This list is non-exhaustive and allows justification by Member States that are not of purely economic nature.[56]The protection of intellectual property rights falls within the ambit of Article 36 TFEU and could constitute a justified restriction to trade.

---

[49] Judgment of the Court of 11 July 1974, Procureur du Roi v Benoît and Gustave Dassonville, Case C- 8-74, ECLI:EU:C:1974:82 (hereinafter Case C-8-74 Procureur du Roi v Benoît and Gustave Dassonville)
[50] See further, Bernitz U, Kjellgren A p. 299, See also Case C- 8-74 Procureur du Roi v Benoît and Gustave Dassonville,
[51] See, Article 36 TFEU
[52] Regarding this section see Barnard C, p. 36
[53] Judgment of the Court of 20 February 1979, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, Case C-120/7, ECLI:EU:C:1979:42, (hereinafter Case C-120/ *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein)*
[54] See Case C-120/ *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, para. 8
[55] See, Barnard C, p. 171-173.
[56] Barnard C, p. 174.

However, the protection of intellectual property rights may not constitute a measure for arbitrary discrimination or act as a disguise for hindering trade between the Member States. For example, within the EU dividing the market is not allowed as it would compromise the primary aim of the EU, which is to establish an area of free movement of goods and services and effective competition across borders. [57] This will be discussed further below.

2.2.4 EU's Internal Market and Intellectual Property Rights

In general, it could be said that intellectual property rights aim to promote innovation and creativity. The legal texts are based on the notion that the lack of an adequate level of protection of intellectual property, in practice, will decrease the interest for innovation and development. Thus, by giving the proprietor a protected position on the market that can result in an economic gain stimulates innovation and inventing processes.[58]

There are many reasons why the EU has engaged itself in the field of intellectual property law. The EU aims to create a far reaching economic integration by establishing a single market. But, the territorial limitations of intellectual property rights affect the integration process negatively. Furthermore, disparities in the scope and protection of intellectual property rights in different Member States cause difficulties in creating a functioning single market. A primary goal has therefor been to create a "level playing field" so that all the different actors in the different Member States are subjected to similar conditions when it comes to intellectual property rights protection.[59]

The EU's involvement in intellectual property law, is also based on the EU's ambition to enhance Europe's economic and technological development and companies´ international competition power. A strong and well-functioning intellectual property law is considered to advance this ambition. Hence a strive to unify the legislations in the different Member States has been made. Although the road has been long the EU

[57] Regarding this paragraph see Bernitz U, Pehrson L, Rosén J & Sandgren C, *Immaterialrätt och otillbörlig konkurrens*, 14 ed, Jure AB, Stockholm, 2017, p. 407
[58] Bernitz U, et. All. 2017, p. 7
[59] Regarding this paragraph see Bernitz U, et. All. 2017, p. 19

has come a long way with achieving this goal. Various directives have been ratified to harmonize the field of intellectual property law.[60]

The introduction of sector specific legislation such as misleading and comparative advertising took place in the 1980s. By the end of the 1980s, legislation harmonizing patent and trademark laws were adopted. Article 114 TFEU was used as the legal ground for adopting the first Trade Mark Directive [61], and the Trade Mark Regulation[62] was based on EU's subsidiary competence in Article 352 TFEU. After the entry into force of the Lisbon Treaty, the EU's competence to regulate matters concerning intellectual property law has been expressly written into Article 118 TFEU.

An interesting point in this regard is that intellectual property rights are seen as property under EU law. However, Article 345 TFEU states that the Treaties shall in no way prejudice the rules in Member States governing the system of property ownership. Here it can be seen that there is an in-built disparity or more correctly a tension between the regulation of the internal market and intellectual property law. Article 345 TFEU, states that property is a matter concerning Member States but the EU has still chosen to regulate the field of intellectual property law by virtue of Article 118 TFEU. The ECJ has even stated that Article 345 TFEU does not give national legislatures, the power to adopt measures that could affect the principle of free movement when it comes to intellectual property law. [63] This ambiguity only highlights the relationship between the internal market law and intellectual property law.

2.2.5 Competition Law and the Internal Market

The internal market is an area that falls under the shared competences of the EU, however in contrast to the internal market competition law is an area within the

[60] Regarding this paragraph see Bernitz U, et. All. 2017, p. 19
[61] Council Directive No 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks.
[62] Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark.
[63] Granmar C, p. 26 as well as Judgement of the Court of 18 February 1992, *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland*, Case C-30/90 ECLI:EU:C:1992:74 (hereinafter Case C-30/90 *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland*)

exclusive competence of the EU.[64] Thus issues concerning competition law are either dealt with on a national level or on an EU level.

However, competition law still has a close connection to the establishment of an internal market. Behind the principle of the four freedoms and the aim to remove trade barriers lies the main idea that the internal market should be comprised of an area of effective competition between goods and services that move freely between Member States. As a result, the main purpose of competition law within the EU is to create lower prices, provide proper distribution of resources, and achieve an overall prosperity through effective competition. Additionally, the competition rules aim to prevent companies from hindering these objectives by distorting competition through price arrangements, market divisions, abuse of dominant position and so forth.[65]

The most important provision on restricting competition relevant to this paper can be found in Article 101 and 102 TFEU (Previously Article 81 and 82 TEC). The provisions consist primarily of prohibitions against agreements that hinder trade and abuse of dominant position. These rules have vertical direct effect as well as horizontal direct effect between companies.[66]

2.3 Article 101 TFEU

2.3.1 Introduction

One of the most central provisions within competition law is the prohibition of agreements that restrict competition stated in Article 101 TFEU. The Article is divided into three sections. The first section, Article 101 (1) TFEU, provides that agreements or conceited practices between undertakings, or associations of undertakings, that affect trade between Member States are prohibited. Article 101(2) TFEU states that agreements that fall within Article 101(1) TFEU are invalid. Lastly Article 101(3) TFEU provides that under certain circumstances an anti-competitive

[64] See Article 3 TFEU
[65] Regarding this paragraph see Bernitz U, Kjellgren A, 2014 p. 392
[66] Regarding this paragraph see Bernitz U, Kjellgren A, p. 393, See Also Article 101 TFEU and Article 102 TFEU

agreement can be subjected to exceptions to the prohibition under Article 101(1) TFEU.[67]

Before examining this Treaty provision, it is important to note that the scope of Article 101 TFEU, concerns restrictions which affect the trade *between* Member States. This is an important factor in EU competition law as it defines the boundaries covered by EU law and the law of the Member States respectively. In other words, if an undertaking acts in a manner that only affects trade within the Member State itself EU law is not applicable. [68]

2.3.2 Definition of Undertaking

The Treaties do not provide a definition of the word undertaking. Instead it has been up to the ECJ to clarify its meaning. In the case *Höfner and Elsa v Macroton GmbH*[69] the ECJ stated that for the purposes of Article 101 TFEU, an undertaking is an "entity engaged in an economic activity, regardless of its legal status and by the way in which it is financed".[70] Undertakings include privately or publically funded entities, with or without legal personality or even natural persons.[71] Economic activity has been defined as the offering of goods or services on the market.[72] The fact that an organization does not have a profit-motive or economic purpose does not in itself mean that the activity is not economic.[73]

2.3.3 Agreements, Decisions and Concerted Practices

Article 101 TFEU does not touch upon the unilateral conduct of a single company, this falls outside the scope of competition law unless it is a matter of abuse of dominant position, which is regulated by Article 102 TFEU.[74] Article 101 TFEU concerns agreements *between* undertakings and covers a wide range of agreements. Consequently, binding agreements and legally non-binding agreements known as "gentleman's agreements" or other looser forms of agreements fall within the scope

[67] Regarding this section, Bernitz U, Kjellgren A p. 396
[68] Regarding this paragraph see, Whish R, Bailey D, p. 152
[69] Judgment of the Court of 23 April 1991, Klaus Höfner and Fritz Elser v Macrotron GmbH, Case C-41/90, ECLI:EU:C:1991:161 (hereinafter Case C-41/90 Klaus Höfner and Fritz Elser v Macrotron GmbH)
[70] Case C-41/90 Klaus Höfner and Fritz Elser v Macrotron GmbH
[71] Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 502
[72] See Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 502 and Judgement of the Court of 16 June 1987, *Commission v Italy*, Case C-118/85, ECLI:EU:C:1987:283
[73] Regarding this paragraph see Whish R, Bailey D, p. 88
[74] Bernitz U, Kjellgren A, 2014 p. 396

of Article 101 TFEU. In addition, Article 101(1) TFEU does not require that the agreement be put into effect.[75] Furthermore, the prohibition also covers concerted practices. In other words where two or more companies behave in consensus without there being an agreement between them. Whether this form of concerted practice has occurred is a matter of proof, however it is the most common form of practice that occurs. [76]

2.3.4 Preventing, Restricting or Distorting Competition

The term restriction of competition is interpreted widely. It's sufficient for the coordinated behavior to have as an objective to restrict competition. No visible effect on competition such as higher prices has to occur. Article 101(1) lists a couple of restrictions on competition these include; price fixings, controlling markets, market sharing, discriminatory agreements, and agreements containing supplementary obligations that have no connection to the subject of the contract. The said Article distinguishes between "object" and "effect".[77] Where restriction of competition by object is found, no anti-competitive effects need to be shown. Where restriction by object has not been found, an anti-competitive effect has to be demonstrated. In order to do so, an evaluation of the actual or potential effects of the agreement on competition has to be carried out. It involves a comparison between the competitive situation that results from the existence of the agreement, and the situation that would arise without the agreement.[78]

2.3.5 The De Minimis Doctrine

The ECJ has adopted a De Minimis rule regarding Article 101 TFEU. This rule implies that the agreement or conceited practice is not considered a restriction on competition if it does not have an appreciable impact on competition. This only applies when looking at the effects. If the objective is to restrict competition it will still be caught under Article 101 TFEU. [79]

2.3.6 Article 101(3) and Block Exemptions

Despite the wording of Article 101(2) TFEU agreements that are caught under Article 101(1) TFEU are not automatically void. A number of cases have been found to

[75] Regarding this section see further, Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 503
[76] Regarding this paragraph see, Bernitz U, Kjellgren A, 2014 p. 396-397
[77] See Article 101 TFEU
[78] Regarding this paragraph see Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 505
[79] Ibid p. 401

restrict competition but have been considered legal under Article 101(3) TFEU.[80] Article 101(3) TFEU states that the prohibition set out in Article 101(1) TFEU does not apply to agreements that meet four cumulative conditions; agreement that create specified benefits, allow consumers a fair share of the benefits, contains only essential restrictions, and do not cause a substantial eradication of competition.[81]

Article 101(3) TFEU gave rise to the advent of block exemptions, by providing that the prohibition in Article 101(1) TFEU could be declared inapplicable both in relation to agreements and *categories of agreements.* Agreements subject to a block exemption are valid without specific authorization.[82] Certain types of vertical agreements can have economic benefits, that outweigh their anti-competitive effects and therefore Article 101(1) TFEU should not be applicable in such cases. Whether such agreements have economic benefits that outweigh their anticompetitive effects, depends largely on the degree of market power the undertaking has.[83] Hence, most block exemptions contain market share thresholds, above which the exemption is not applicable, as well as a list of hardcore restraints that disqualify the whole agreement.[84] It can be presumed that the market share held by the undertakings involved in the agreement should not exceed 30 %.[85] It is important to note that even if the conditions for block exemptions are met, the Commission may still decide that the exemption is not applicable if the effects of the agreement are incompatible with Article 101(3).[86]

[80] Jones A, *The Journey towards an effect-based approach under Article 101 TFEU- the case of hardcore restraints*, The Antitrust Bulletin: Vol. 55, No. 4/ Winter 2010 p. 785
[81] Regarding this paragraph see, Jones A, p. 785 Some forms of restriction on competition fall within a category of hard core cartels and are blacklisted. This blacklisted restrictions always fall within Article 101 and are always prohibited. These include, price cartels, production quotas, geographic and customer based division of markets. See Bernitz U, Kjellgren A, 2014 p. 396-397.
[82] Whish R, Bailey D, p. 178
[83] Commission Regulation (EU) No 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices (Text with EEA relevance)
[84] Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 507
[85] Regarding this paragraph see Commission Regulation (EU) No 330/2010
[86] Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 507

2.4 Article 102 TFEU

2.4.1 Introduction

Article 102 TFEU is another important provision alongside Article 101 TFEU. Article 102 TFEU deals with the unilateral behavior of dominant firms acting in an abusive manner.[87] The said Article provides that any abuse by one or more undertakings in a dominant position within the internal market, shall be prohibited in so far as it affects trade between Member States.[88] Under Article 102 TFEU, undertakings in a dominant position have a "special responsibility" to not allow their behavior on the market to impair competition.[89] Article 102 TFEU provides a list of measures that can be considered abusive. These forms of abuses consist of unfair purchase or selling conditions, limiting production, discriminatory behavior and making the conclusion of contracts subject to acceptance of supplementary obligations by the other party.[90]

2.4.2 Definition of Undertaking

The term "undertaking" has the same meaning in Article 102 TFEU as it does in Article 101 TFEU.[91] However, Article 102 TFEU does not specify what is meant by one or more undertakings. Reasonably, there should be some sort of economic connection or level of dependency between the undertakings in order to create a dominant position within the market.[92]

2.4.3 Determining Dominance

Article 102 TFEU applies only when one undertaking has a dominant position or when two or more undertakings have a dominant position collectively.[93]As can be noted, similarly to Article 101 TFEU in order for EU law to be applicable the abuse of dominant position must affect inter-state trade. A dominant position within the market is not in itself prohibited, however the unilateral behavior of a dominant undertaking can affect competition, and such a behavior is prohibited under Article 102 TFEU.[94]

---

[87] Whish R, Bailey D, p. 183
[88] See Article 102 TFEU
[89] Nissen M, Van de Walle de Ghelcke G, Vilarasau M, Competition Law in the Pharmaceutical Sector, Guide to EU Pharmaceutical Regulatory Law, Chapter 15, 2010, p. 510-511
[90] Whish R, Bailey D, p.183
[91] Whish R, Bailey D, p.188
[92] Bernitz U, Kjellgren A, 2014 p. 409
[93] Whish R, Bailey D, p. 190
[94] Bernitz U, Kjellgren A, 2014, p. 409

Dominance in EU law is defined as a position of economic strength enjoyed by an undertaking, which allows it to prevent effective competition, as it has enough power to act independently of its competitors, customers and consumers.[95] An important factor in determining market dominance is the company's market share.[96] Dominance is presumed when the company has more than 50% of the market shares. However, in rare cases dominance can occur below this share.[97] Furthermore it must be established that the undertaking has a dominant position in the whole or substantial part of the internal market.[98]

2.4.4 Relevant market

Another important aspect when determining dominance is establishing the relevant product market. By defining the market, one is capable of identifying the boundaries of competition between firms. The main purpose of defining a market, both geographically and in terms of product, is to determine the actual competitors involved that can possibly distort competition. The following definitions have been made and developed by the Commission.[99]

A relevant product market is comprised of all products or services which are regarded as interchangeable or substitutable by the consumer, based on the products characteristic, price and intended use. [100]The relevant geographical market is defined as the area in which the undertaking is involved in the supply and demand of products, in which the conditions for competition can be distinguished from neighboring areas. Hence, the relevant market in which the competition takes place is a combination of the relevant product market and the relevant geographical market.[101]

[95] Whish R, Bailey D, p. 190
[96] Bernitz U, Kjellgren A, 2014, p. 410
[97] See further regarding this paragraph, Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 511
[98] Whish R, Bailey D, p.199
[99] Regarding this paragraph see, Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 499-500
[100] Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 500
[101] Regarding this section see, Commission Notice on the definition of relevant market for the purposes of Community competition law (97/C 372/03). See also Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 500

2.4.5 Relevant Market in the Pharmaceutical Sector

When it comes to the relevant market for pharmaceuticals, the relevant product market is defined slightly differently and it is a bit more complex.[102] One issue that arises is that the pharmaceutical market has an abundancy of generic products, and the question is whether these products are also competing with the original pharmaceutical products. In some cases, perfect substitutes are not available for a certain specific ailment and establishing the relevant market is even more difficult in these cases.[103] The relevant product market for pharmaceuticals is based on the Anatomical Therapeutic Classification (ATC) system which divides these pharmaceutical drugs into groups. The groups are classified according to the organs or systems which they act on, and their chemical, pharmacological and therapeutic properties which are then divided into 5 different levels. [104] The geographical markets for medicinal products remains national, due to the differences in administrative procedures, purchasing and reimbursement policies. [105]

3. Parallel trade

3.1.1 Definition of Parallel Trade

Parallel importation occurs when intellectual property protected products from one Member State are imported into another Member State, outside the manufacturers distribution system without its consent. Member States tend to have different prices on the same product due to different forms of regulations set by the government. These price differences allow companies to purchase a product in one Member State at a low price and sell it in another country at a higher price, generating profit. Consequently, it is said that parallel trade creates healthy competition and reduces prices for consumers, it is also a direct result of the EU's aim to establish an area of free movement of goods.[106]

---

[102] Hunter, R.G. *The pharmaceutical sector in the European union – Intellectual property rights, parallel trade and community competition law*. Institutet för Europeisk rätt vid Stockholms Universitet, Jure AB, Stockholm, 2001, p. 54
[103] Regarding this section see further, Hunter R, p. 54
[104] Liberatore F, p. 350
[105] Nissen M, Van de Walle de Ghelcke G, Vilarasau M, p. 500-501
[106] Regarding this paragraph see, Europeiska kommissionen. Generaldirektoratet för näringsliv, p. 23

It is important to note that parallel trade does not entail unofficial, illegal, or informal sector activities. Furthermore, parallel trade is not the trade of pirated or counterfeit goods. Pirated and counterfeit goods are unauthorized versions of products that violate intellectual property rights. Parallel imports on the other hand are genuine often branded goods that do not infringe intellectual property rights. However, the importation of the product from one country to another may not be authorized by the right holder. Parallel imports may be packaged differently or lack the original manufacturers' warranty, but they will otherwise be the same as the official import being marketed locally. [107]

3.1.2 Parallel Trade with Pharmaceutical Drugs

The EU aims to achieve two major objectives in its policies regarding pharmaceuticals. It seeks to secure a high level of public health and innovation, whilst providing support for a competitive industry that ensures a constant supply of new medicines. This requires that the access to medicine and treatment is affordable and that the medicines are safe, whilst simultaneously maintaining the competitiveness of the European pharmaceutical sector.[108]

According to Article 168 TFEU, it is the Member States that are solely responsible for the organization and delivery of national health services.[109] Since states are the real consumers that pay for prescription drugs and are responsible for making sure that health expenditures do not become excessive it is in their interest to contribute to the price setting. Different states have different rationales behind their health policies and hence set their prices differently.[110]

[107] Regarding this paragraph see Matthews D and V Munoz-Tellez. *Parallel Trade: A User's Guide. In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices,* 2007 p. 1429

[108] Regarding this section see, Hancher L, *The pharmaceuticals market: parameters and pathways, Health Systems Governance in Europe: The Role of EU Law and Policy*, Cambridge University press Ch15, 2010 p. 635

[109] Aile S, Parallel Trade in Pharmaceuticals: Reconsidering the Underlying European Community Policies, Commentary on the Opinion of AG Francis Jacobs in Case C-53103 Bayer/Adalat, *European Journal of Law Reform.* Vol. VII, no. 3/4, Eleven International Publishing 2006, p. 485

[110] Regarding this paragraph see, Aile S, p. 485-486

Parallel trade of pharmaceutical drugs has occurred in Europe since the 1970s. At the time, parallel importation was not governed by any regulations or Treaties.[111] However, the notion was supported by Articles 28-30 TEC[112] (current Articles 34-36 TFEU) which established the right to free movement of goods between Member States in the European Community. Although it has existed since the 70's parallel trade was a rare occurrence, it was not until the 1990s when parallel importation became a lucrative business.[113]

As mentioned, parallel traders operate outside the manufacturers distribution network. Parallel traders seek to take advantage of the price differences to purchase goods in low price markets and resell them in higher price markets at a discount. Often, medicinal products are covered by patent rights, and the packaging is covered with trademark rights. In order to comply with the exporting markets legislation on pharmaceutical drugs, parallel importers usually have to repackage the goods, to meet the required standard.[114]

3.1.3 Patent Law

In order to better understand the notion of parallel trade and consequently the principle of exhaustion of intellectual property rights, it is of use to understand the more specific EU legislations regarding patent and trade mark. As early as the 1960s the EU began its process of creating a unitary, supra-national patent for the whole EU community.[115] These efforts resulted in the European Patent Convention (EPC) which came into force in 1977 and the establishment of the European Patent Office (EPO). The conventions main aim is to unify requirements and methods for granting patent in the EU, however, it does not provide automatic protection in all Member States. As a result, inventors can either file a patent in each state or file a single patent with the EPO.[116]

---

[111] Riksförsäkringsverket *Parallellimporterade läkemedel: inte till vilket pris som helst,* Stockholm, 2000 p. 10
[112] Treaty Establishing the European Community (consolidated version 2002), O.J. C 325
[113] Regarding this paragraph see, Riksförsäkringsverket 2000 p. 10
[114] Regarding this section see JA kemp Briefing, Parallel Imports of Pharmaceutical Products in the European Union: When Can Goods be Re-packaged and Re-branded, 2014 p. 1-2
[115] Bernitz U, et. all. 2017 p. 167
[116] Regarding this paragraph see further, Yarsky JK, *Hastening Harmonization In European Union Patent Law Through A Preliminary Reference Power*, Boston College International & Comparative Law Review, Vol. 40. Issue.1 2017, p. 169

In 2012 two regulations were passed establishing the European Patent of Unitary Effect (EPUE). The EPUE allows an inventor that has a patent granted by the EPO to receive automatic protection in all Members of the Unified Patent Court Agreement. In other words, the EPUE serves as an alternative third route to receiving a patent in Europe once it comes in force.[117] However the EPUE has not come into force and the fate of the Court is still uncertain with the exit of Britain from the EU.

Patents on medicinal products may cover the method of production, the active ingredient or use of a substance. The duration of a patent is usually twenty years, however for medicinal products this time frame can be extended for five additional years.[118] The EU has harmonized the law regarding biotechnical inventions by the Patent Directive on the Legal Protection of Biotechnical Inventions.[119] As for medicinal products, Regulation (EC) No 469/2009[120] concerning supplementary protection for medicinal products, has been adopted. Although there have been various secondary legislations that have harmonized certain fields of EU patent law, directives and regualations do not touch upon parallel trade and the principle of exhaustion. Nonetheless when it comes to European patents the principle of exhaustion is still applicable.[121]

3.1.4 Trade Mark Law

Trade mark rights has been an area within EU law that has been harmonized by the European Trade Mark Directive[122] and the Trade Mark Regulation[123]. Under Article 10 of the Trade Mark Directive, the proprietor of the trade mark has exclusive rights, that can be infringed when a third party uses that trade mark without the proprietor's consent. Article 15 of the said Directive sets out limitations to the proprietor's

[117] Ibid p. 171
[118] Von Feld Ina, Neels Philipp, *Parallel Trade, Guide to EU Pharmaceutical Regulatory Law*, Chapter 14, Editor, Shorthose S, 2010, p. 471
[119] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
[120] Regulation (Ec) No 469/2009 of The European Parliament and of the Council, of 6 may 2009, concerning the supplementary protection certificate for medicinal products. This Regualtion provides five additional years of protection for pharmaceutical patents.
[121] Bernitz U, et. All, 2017, p. 170
[122] Directive (EU) No. 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks
[123] Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015

exclusive rights; "The trade mark does not provide the proprietor the right to prevent its use in relation to goods which have been put on the market, by the proprietor or with his consent." The second paragraph provides that where there exists legitimate reason for the proprietor to oppose further commercialization of goods, especially when the goods have been changed or impaired the proprietor may claim that his exclusive trademark rights have been infringed.[124] This is an exception to the exhaustion principle. The exhaustion principle will be discussed further below.

3.2 Exhaustion Principle

Initially national intellectual property rights were a category that fell outside the scope of EU law as these rights were regulated by national law and were limited in territory. However, the existence of different national laws regarding intellectual property rights was not sustainable as it stood in conflict with the EU's aim of a single market and an area of free movement of goods.

In the case *Consten & Grundig*[125] the ECJ recognized the fact that national intellectual property rights should be respected, even if they to a certain extent hinder the free movement of goods.[126] The case dealt with the grant of exclusive trade mark and distribution rights of televisions and tape recorders that Grundig had conferred on its exclusive distributor, Consten, in France. When parallel traders began competing with Consten's prices in France, Consten started a trademark infringement process and unfair competition action under French law to prevent the parallel imports. The ECJ found the distribution agreement unlawful as it resulted in an isolation of the French market and aimed at protecting Consten's pricing of Grundig's products. The ECJ stated that the prohibition of Article 101 TFEU, would be ineffective if Consten could use the trademark as a way to achieve the same objective pursued by the exclusive distribution agreement, which had been held to be unlawful. As a result, the use of trademark rights as a tool to divide national markets amongst distributors is not

[124] See, Article 15 Directive (EU) No. 2015/2436
[125] Judgment of the Court of 13 July 1966, Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community. Case C-56/64, ECLI:EU:C:1966:41(hereinafter Case C-56/64 Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community.)
[126] Lidggard HH, Parallelhandel: Konsumtion av immaterialrätt i Europa och USA, Norstedts Juridik, 2002, p. 59-60

part of the essential function of the trademark and is therefore prohibited under the Treaties.[127] Here the ECJ distinguishes between having an intellectual property right and using the intellectual property right. It is the use of the intellectual property right that can consequently be incompatible with EU's objective of creating an internal market with effective competition.

A pivotal case that further clarified the application of the exhaustion principle was the *Centrafarm v Sterling*[128] case. In the *Centrafarm v Sterling* case, Sterling a drug manufacturer, had a patent for the process of preparing acidum nalidixicum in various Member States. The patent owner placed a drug containing this process in the UK and west Germany. Centrafarm then imported the patented drug to the Netherlands for a lower price. Sterling brought action against Centrafarm for its marketing efforts. The ECJ found that Article 36 TFEU only allows derogations from the free movement of goods when such derogations are justified for safeguarding rights constituting the specific subject matter of the intellectual property right.[129] When it comes to patents, the specific subject matter is that the patentee is guaranteed the exclusive right to use an invention with a view to manufacture industrial goods, and place them on the market for the first time as well as oppose infringements.[130] The ECJ confirmed that the patent holders' rights are exhausted once the products are placed on the market for the first time in any Member State.[131] The ECJ essentially concludes in this case that a derogation from Article 36 TFEU is not justified if the product has been placed in a Member State with the right holder's consent.[132]

---

[127] Regarding this case see Braun D, Ritter L*, European Competition Law- A Practitioner's Guide*, Kluwer Law International, 3rd edition, 2004, p. 732, as well as Case C-56/64, Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community.

[128] Judgment of the Court of 31 October 1974 Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc., Case C- 15/74. ECLI:EU:C:1974:114

[129] Case C- 15/74, Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc para. 8

[130] Case C- 15/74, Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc para. 9

[131] Regarding this case see Gold MA, European patent law and exhaustion principle, University of Chicago Legal Forum, Volume 1992 Issue 1, Article 19, 1992, p. 443-444, See also Case C- 15/74, Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc. (the principle of specific subject matter applies to all intellectual property rights, see Judgement of the Court of 8 June 1971 *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG*, Case C-78/70, ECLI:EU:C:1971:59

[132] Case C- 15/74, Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc para. 11

According to the ECJ the principle of exhaustion even applies to situations where products are placed in a Member State where patent protection is unobtainable.[133] This situation was dealt with in the *Merck v Stephar*[134] where the ECJ stated that if a proprietor chooses to market a product in a Member State where protection cannot be obtained, he or she must accept the consequences of his choice as regards to the principle of free movement of goods. Pharmaceutical companies must thus blame themselves if they chose to market their products in countries where they cannot enjoy protection and they cannot rely on the patent rights they have in other Member States.[135]

3.2.1 Definition of Exhaustion Principle

Over the years the ECJ has put focus on the free movement of goods and concretized the principle known as the European exhaustion principle of intellectual property rights. The principle implies that a product covered by intellectual property rights, placed on the market within an EU Member State, with the consent of the proprietor, can as a general principle freely circulate and be resold within the EU without being hindered by any intellectual property right that it contains. [136]

3.2.2 Consent

The meaning of consent was addressed in the joint cases *Davidoff and Levi Company*.[137] In the said cases the ECJ concluded that a proprietor's consent to marketing within the EU may be implied. However, an implied consent cannot be assumed by the fact that the proprietor has not communicated to all purchasers his or her opposition to marketing or imposed any contractual reservations. Likewise, it cannot be assumed that an implied consent exists form the fact that the goods carry no warning of prohibition. [138]

---

[133] Von Feld Ina, Neels Philipp p. 472
[134] Judgment of the Court of 14 July 1981, *Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler*, Case C-187/80, ECLI:EU:C:1981:180 (hereinafter Case C-187/80, *Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler)*
[135] Case C-187/80, *Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler*
[136] Ibid
[137] Judgment of the Court of 20 November 2001, Zino Davidoff SA v A & G Imports Ltd and Levi Strauss & Co. and Others v Tesco Stores Ltd and Others, Case C-414/99 to C-416/99 ECLI:EU:C:2001:617 (hereinafter C-414/99 to C-416/99, Zino Davidoff SA v A & G Imports Ltd and Levi Strauss & Co. and Others v Tesco Stores Ltd and Others)
[138] Case C-414/99 to C-416/99, Zino Davidoff SA v A & G Imports Ltd and Levi Strauss & Co. and Others v Tesco Stores Ltd and Others

3.2.3 Who is the Proprietor?

Another issue that arises with parallel import, is the question of who is the proprietor? This question was discussed in the *HAG*[139] case. The *HAG* case concerned the German company HAG GF AG, producer and distributor of coffee, decaffeinated by a process of its own invention. In 1908 HAG, registered two trade marks in Belgium which included the proprietary name Kaffee HAG. It later established a subsidiary company in Belgium trading as Kaffee Hag SA. HAG GF controlled and owned the subsidiary fully and eventually transferred the trademarks registered in its own name to its subsidiary. The subsidiary also registered two trademarks, one of which included the proprietory name Café HAG. Café HAG SA assigned its trademarks to Van Zuylen Freres, whom later changed name to SA CNL–SUCAL and began importing decaffeinated coffee into Germany under the proprietory name "HAG". In order to prevent such importation HAG GF AG, claimed that Kaffee HAG had become a well-known brand name in Germany and the decaffeinated coffee it makes under that name is superior in quality to the imported decaffeinated coffee by SA CNL –SUCAL due to the manufacturing process. The ECJ stated that an undertaking can oppose the importation of goods from another Member Sate bearing an identical trade mark or similarly confusing trade mark even if the imported trade mark originally belongs to a subsidiary of the undertaking opposing the importation. [140]

In other words, every trademark owner can object to the importation of similar or identical trademark as the owner regardless of the fact that the importing company originally belonged to the trade mark owner. [141] Although this case does not deal exactly with the same type of parallel importation that is discussed in this paper, it does shed some light on who the proprietor is and who can prevent the further commercialization of goods.

3.2.4 Territorial Limitations of the Exhaustion Principle

As mentioned the exhaustion principle is based on the principle of free movement between states, and thus only applies to products marketed by the right holder or with

---

[139] Judgment of the Court of 17 October 1990, *SA CNL-SUCAL NV v HAG GF AG,* Case C-10/89, ECLI:EU:C:1990:359 (hereinafter Case C-10/89, *SA CNL-SUCAL NV v HAG GF AG)*

[140] Case C-10/89, *SA CNL-SUCAL NV v HAG GF AG,* para. 19

[141] Monaco AL, *The Role of Consent and Consumer Protection in Reconciling Articles 30 and 36 in Hag I and Hag II*, Fordham International Law Journal Volume 15, Issue 1, 1991, Article 6, p. 215

its consent in one of the Member States and the members of the European Economic Agreement.[142]

However, if the products are imported from third countries i.e. in countries outside the EU, the exhaustion principle only applies once the products are in free circulation in the EU, in other words after being put on the market by the right holder or with its consent. This was confirmed by the ECJ in the *Silhouette*[143] case. The *Silhouette* case concerned the importation of spectacles by an Austrian right owner to a distributor in Bulgaria (a non-EU member State at the time) with an explicit export ban. However, the spectacles were re-imported by an Austrian dealer. The ECJ found that Article 7 of the Trade Mark Directive does not consider national trademark rights exhausted when the products have been placed on the market outside of EU/EEA.[144] Hence parallel imports from countries outside the EU/EEA can be halted by the use of trademark rights. The Treaties do not provide for a worldwide exhaustion principle, only a regional one. [145]

3.3 Exhaustion Principle and Trade Marks

The exhaustion principle is a little bit special and as mentioned before there is secondary legislation concerning the exhaustion principle and trade mark law. Therefor, special attention should be given to the *Bristol-Myers*[146] case where the ECJ dealt with the exhaustion of trademark rights. The case concerned owners of trademark rights covering pharmaceutical drugs preventing parallel importers. The

[142] This is due to the fact that the EEA agreement is directly applicable law that contains the same principles as stated in treaties, extending the exhaustion principle to the EEA countries. Therefor the Courts ruling also applies to situations where the protected product has been placed on the market in any EEA country. The EEA countries include(Norway, Iceland and Lichtenstein. See further Braun D, Ritter L, p. 737

[143] Judgment of the Court of 16 July 1998, Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH, Case C-355/96, ECLI:EU:C:1998:374, (hereinafter Case C-355/96 Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH)

[144] See Case C-355/96 Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH, See also Braun D, Ritter L, p. 737

[145] Braun D, Ritter L, p. 737-738

[146] Judgment of the Court of 11 July 1996, *Bristol-Myers Squibb v Paranova A/S and C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S and Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S,* Cases C-427/93, C-429/93 , C-436/93, ECLI:EU:C:1996:282 (hereinafter Case C-427/93, *Bristol-Myers Squibb v Paranova A/S)*

ECJ stated that under certain circumstances a pharmaceutical company can prevent parallel import of repackaged pharmaceutical drugs under current Article 15 of the Trade Mark Directive.[147] However, if certain conditions are met for example if the repackaged product does not damage the reputation of the trademark owner and the packaging clearly states who the original manufacturer is, then the pharmaceutical company cannot prevent parallel import of repackaged products.[148] As can be seen from the *Bristol-Myers* case, although the principle of free movement is highly valued within the EU, derogations can be made from it. The field of intellectual property law is a constant interplay between competition law, consumer protection and unfair competition. In the ECJ's ruling the ECJ highlights the importance of consumer protection. By setting certain conditions that have to be met for importing repackaged goods, the ECJ is ensuring that the end consumer is not misled in anyway by parallel importation.[149] This line of reasoning is in accordance with the objectives set out in Directive 2005/29/EC.[150] The purpose of the said Directive is to ensure a high level of consumer protection within the EU. The Directive aims to approximate national laws regarding unfair commercial practices that can harm consumers economic interests.[151]

Furthermore, the *Bristol-Myers* case also highlights another aspect closely related to intellectual property right and that is, reputation. The ECJ states that the parallel importer must ensure that the reputation of the trade mark and consequently its owner does not suffer any inappropriate presentation of the repackaged product.[152] Here the ECJ paves the way for another derogation from free movement of goods.[153] The health care sector is a particularly sensitive area, in which the public's confidence in the medicine and healthcare in general is closely related to the quality, integrity and the presentation of the product. Hence poor quality or untidy packaging could result

[147] At the time Article 7(2) Directive 89/104/EEC
[148] Three other conditions have to be met, they are as follows: The importer of the repackaged product notifies the trademark owner, before the repackaged product is sold. repackaging is necessary for marketing the product in the country of destination. It does not have any effects on the original condition of the product inside the package, See Case C-427/93, *Bristol-Myers Squibb v Paranova A/S*
[149] Case C-427/93 Bristol-Myers Squibb v Paranova A/S para.67
[150] Directive 2005/29/EC of The European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market 2005 O.J. L 149/22 (hereinafter Directive 2005/29/EC)
[151] See Article 1, Directive 2005/29/EC
[152] Case C-427/93, *Bristol-Myers Squibb v Paranova A/S para. 75*
[153] Case C-427/93 Bristol-Myers Squibb v Paranova A/S para.75

in damage to the trade mark's reputation.[154] The ECJ's line of reasoning touches upon another closely related aspect to consumer protection and that is unfair competition. The ECJ highlights the fact there is an issue of reputation involved even when pharmaceutical products are repackaged and imported. In this case the ECJ's reasoning is in line with the Directive 2006/114/EC[155]. The Directive aims to protect traders against misleading advertisement and the unfair consequences of such behavior.[156] The ECJ seems to touch upon that although parallel trade in the field of pharmaceuticals is very well desired and permitted, the activity may not result in damaging other pharmaceutical company's reputation or piggy backing.

3.4 Relationship Between Competition Law and Intellectual Property Law

As can be seen from the cases above there is a special relationship between Intellectual property law and competition law. Intellectual property rights confer certain rights on their proprietors and they serve as powerful tools both legally and economically. The essential characteristics of intellectual property rights are that they give the owners a right to exclude others or prevent others from behaving in a particular way. Patent for example grants the owner the right to prevent others from producing the patented goods, or applying the same process for 20 years. [157] Consequently this powerful tool interacts with other fields of law, competition law being one of them. Competition law aims at combating market monopolies and enhancing effective competition and keeping markets open. Naturally one might think that there is constant tension in the relation between competition law and intellectual property rights. [158] However, this view is not completely accurate. In competition law, an authority is intervening against the *behavior* of certain companies. This has nothing to do with the scope of intellectual property rights. Competition law does not narrow down the scope of intellectual property law. It is the use of the intellectual property right, that can give rise to a situation that falls under the competition rules, if

[154] Case C-427/93 Bristol-Myers Squibb v Paranova A/S para.76
[155] Directive 2006/114/EC Of The European Parliament And Of The Council of 12 December 2006, concerning misleading and comparative advertising 2006 O.J. L 376/21 (Hereinafter Directive 2006/114/EC)
[156] See Article 1 Directive 2006/114/EC
[157] Whish R, Bailey D, *Competition Law*, 8th edition, Oxford University Press, 2015 p. 812
[158] Malaga M, The European Patent with Unitary Effect, - Incentive to Dominate? A look From the Compeition Law Viewpoint. European intellectually property rights, 2014, p. 138

the use extends what is deemed necessary to obtain the legitimate protection of the intellectual property right.[159]

In general, one could say that there has been a strive within the EU to strike a balance between the positive competitive effects and the anti-competitive effects that intellectual property rights bring. However, it has not been possible to balance out all the anti-competitive effects of intellectual property rights, solely within the field of intellectual property law. This is where competition law has come into play, serving as a complementary legal framework to fill in the gaps of intellectual property law. [160]This topic will be discussed further in chapter four.

3.5 Summary

Parallel trade occurs when pharmaceutical products are bought in one Member State at a low price and sold in a high priced Member State at a discount. Parallel trade is completely legal under Article 34 TFEU, which prohibits quantitative restrictions or measures having equivalent effect. The problem is that these pharmaceutical drugs are usually protected by intellectually property rights usually in the form of patents and trademarks. Intellectual property rights aim to prevent third parties from exploiting the proprietor's products without authorization and consequently serve as a potential barrier to parallel trade.[161] Therefor the ECJ has adopted the principle of exhaustion. The ECJ has stated that once a product has been placed within the EU market, with the consent of the property right owner, he or she cannot prevent, further commercialization of the product. In other words, the proprietor's rights are exhausted and the free movement of goods is made possible.[162] Consequently, pharmaceutical companies are facing competition by their own products as they struggle with justifying restrictions to parallel trade.

[159] Bernitz U et. all, 2017, p. 400, See, Judgment of the Court of 6 of December 2012, AstraZeneca v Commission, Case C-457/10 P, ECLI:EU:C:2012:770
[160] See further Bernitz et. Al. 2017 p. 400
[161] Von Feld Ina, Neels Philipp p. 472
[162] Von Feld Ina, Neels Philipp p. 472

4 Competition Law Cases

4.1 Dual Pricing

Over the years, the ECJ has encountered various forms of agreements that have created potential restrictions on trade. One of the most famous cases, dealt with dual pricing schemes and whether this arrangement was allowed under Article 101 (3) TFEU. Dual pricings schemes are agreements set out by pharmaceutical manufactures and their wholesalers in which different prices are applied depending on where the wholesalers eventually sell the pharmaceutical product. Lower prices are applied in the domestic market and higher prices are set on the product that are exported to other Member States. [163] Dual pricing arrangements was the focal point of the *GlaxoSmithKline case.*[164]

In 1998 Glaxowelcome (now GlaxoSmithKline) notified the commission of its new sales condition, seeking to get an approval of exemption under Article 81(3) (now Article 101(3) TFEU). GlaxoSmithKline (GSK) had established two pricing arrangements. The products for sale in Spain to wholesalers would have the same price as those set by the Spanish health authorities. On the other hand, products exported to other Member States would be sold at a price set by GSK, which was higher than the regulated price in Spain. By doing so GSK limited parallel trade from Spain to other Member States, especially the UK. In the *GlaxoSmithKline* case the Commission found that the dual pricing scheme restricts parallel trade, as wholesalers were forced to purchase the drugs at a higher price than the maximum price for the national sale. The case was challenged by GSK before the Court of First Instance (CFI).

The CFI found that a dual pricing system was not a restriction of competition by object, and therefor, an assessment of its effects must be made. The Commission appealed to the ECJ. The court of justice did not agree with the CFI and stated that a dual pricing system aiming to restrict parallel trade is a restriction by object. Therefor it is not necessary to assess its effects. However, it went on further by stating that a

[163] Regarding this paragraph see Liberatore F, p. 352
[164] Judgment of the Court of 6 October 2009, GlaxoSmithKline Services Unlimited v Commission of the European Communities Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, ECLI:EU:C:2009:610, (hereinafter Case C-501/06, GlaxoSmithkline Services Unlimited v Commission)

dual pricing system could be exempted under Article 101(3) TFEU if its economic benefits outweigh its anti-competitive effects.[165]

As can be noted from the case above dual pricing system is a restriction of competition by object under Article 101(1) TFEU. However, the system can be considered an exemption under Article 101(3) TFEU. Here it is evident that the ECJ is taking into account the negative effects of parallel trade, such as loss in material efficiency, negative impact on technical progress and limited benefit to the consumer. The ECJ recognizes that dual pricing systems can eliminate the inefficiencies related to parallel trade.[166] This reasoning is in line with the main objective of establishing an area of effective competition.

4.2 Supply Quota System by a Non- Dominant Company

A supply quota system entails a supplier either ceasing to meet orders from wholesalers or, more commonly, minimizing the supply quota in so far that only enough products to cover the domestic sales are provided to the wholesalers. In other words, there are no "excess products" available for parallel trade.[167] In some cases, the supplier happens to have a dominant position on the market or a non-dominant position on the market. The *Bayer/Adalat*[168] case involved a supplier who was not in a dominant position.

The *Bayer/Adalat case* concerned the refusal to supply the drug Adalat designed to treat cardiovascular diseases. Bayer AG (hereinafter Bayer) was a parent company, manufacturing and marketing the drug Adalat and had subsidiaries in all Member States.

In most Member States the price of Adalat is fixed directly or indirectly by national health authorities. During the period 1989 to 1993, the prices fixed for Adalat in

[165]Regarding this case see Liberatone F, p. 352 and Case C-501/06, GlaxoSmithkline Services Unlimited v Commission
[166] Compare Liberatore F, p. 353
[167] Regarding this paragraph see Liberatore F, p. 353
[168] Judgment of the Court of 6 January 2004. Bundesverband der Arzneimittel-Importeure eV and Commission of the European Communities v Bayer AG, Case C-2/01 P and C-3/01 P, EU:C:2004:2 (hereinafter Case C-2/01 P and C-3/01 P, Bundesverband der Arzneimittel-Importeure eV and Commission of the European Communities v Bayer AG.)

Spain and France were on average 40% lower than the prices in UK. Due to this price difference wholesalers from Spain and France exported Adalat to the UK from 1989 and onwards. According to Bayer sales of Adalat by its British subsidiaries, (Bayer UK) was cut by almost half between 1989 to 1993 due to the parallel import resulting in a loss of Dem 230 million for the British subsidiary. The total loss of revenue for Bayer was 100 million DEM. To prevent this, the Bayer group changed its supply policy and began to cease meeting its increasing large orders placed by Spanish and French wholesalers with its Spanish and French subsidiaries. The Commission concluded that the Bayer group had infringed Article 101 of the TFEU, by imposing an export ban as part of their commercial relation with their wholesalers.

However, the CFI did not agree with the Commission's take. Instead the CFI stated that the Commission had not proved, based on the attitude and conduct of the wholesalers that there was an agreement between the undertakings. The Commission's finding that the wholesalers had aligned their conduct in accordance with the export ban failed on factual grounds as the Commission could not prove that Bayer had imposed an export ban or that supplies were made conditional on compliance with the export ban. In other words, the Commission failed to establish that Bayer demanded or negotiated a particular line of conduct with the wholesalers concerning the destination of export of Adalat, and penalized exporting wholesalers. Nor had the commission established that the wholesalers had acted in accordance with the alleged ban, on the contrary the wholesaler demonstrated firm intention to continue carrying on their parallel exports to the UK. As a result, the CFI found that there was no agreement under Article 101 TFEU between Bayer and its Spanish and French wholesalers to limit parallel export to UK. The ECJ confirmed the judgment of the CFI.[169]

The outcome of the ECJ's judgement is quite interesting as it provides leeway for pharmaceutical manufacturers to prevent parallel trade. This case suggests that a pharmaceutical manufacturer who is not in a dominant position may adopt a supply

[169] See Case C-2/01 P and C-3/01 P, Bundesverband der Arzneimittel-Importeure eV and Commission of the European Communities v Bayer AG.

quota system that restricts competition and affects inter-State trade as long as there is no consensus between him and the wholesalers.[170]

4.3 Supply Quota System by a Dominant Company

In the *Syfait 1*[171] case the question arose whether a dominant pharmaceutical company's refusal to supply constituted an abuse of dominant position under Article 102 TFEU. GlaxoSmithKline and its subsidiary GSK AEVE established in Greece imported and distributed medicinal products, which were then sold to various wholesalers whom distributed them on the Greek market and abroad. At first, GSK AEVE met all its order which it received. Most of the supplies corresponding to those orders were re-exported to other Member States, UK included. This was due to the fact that these medicinal products were sold for much lower price in Greece. However, after some time, GSK AEVE changed its distribution system and stopped meeting orders from their wholesalers. Instead they supplied hospitals and pharmacies directly. GSK AEVE claimed that this change in the distribution system was made because the significant shortages of these medicinal products was being experienced in the Greek market, due to the re-exportation of these products by third parties. Shortly after the supply of medicinal product normalized on the Greek market, GSK AEVE changed its sale system again. However, it did not meet all its orders as it had done before.[172]

The wholesalers of GSK AEVE, *Syfait* and others, brought action against GSK AEVE claiming that the company had not met its order and that such conduct was an abuse of dominant position under Article 102 TFEU. However, The ECJ found that it had no jurisdiction to examine this question. It stated that the Greek Competition Authority was not considered a referring court or tribunal as it lacked independence and its judgment would not render into a judicial decision. As a result, the Greek Competition Authority could not ask for a preliminary ruling by the ECJ. Hence the

[170] Liberatore F, p. 354
[171] Judgment of the Court of 31 May 2005 Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE, Case C-53/03, ECLI:EU:C:2005:333 (hereinafter Case C-53/03 Syfait and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE)
[172] See Case C-53/03 Syfait and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE

question was never examined. However, the General Advocate Jacobs discussed this issue in an Opinion[173] that caused a lot of debate.

The Advocate General stated that a refusal to supply is capable of objective justification and hence is not an abuse due to the circumstances of the European pharmaceutical sector at the current stage of its development. More specifically, the fact that States intervene in fixing prices at a lower level than in other countries giving rise to parallel trade, the negative consequences of parallel trade for competition, the fact that end consumer may not in all cases benefit from parallel trade are all factors that need to be considered. [174]

In *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE*[175] case (Syfait 2) the wholesalers, Syfait and others brought action in the court in Greece. This case is the continuing saga of *Syfait 1*. The appellate court in Greece asked for a preliminary ruling from the ECJ and raised the same questions the Greek competition authorities had made. This time the ECJ found that it did have jurisdiction. However, it did not take the same approach that Advocate General Jacobs had made in his opinion four years before. Instead the ECJ stated that an undertaking in dominant position on the relevant market refuses to meet its ordinary order by wholesalers, as a way to prevent parallel export carried out by those wholesalers, is abusing its dominant position. It is up to the national courts to determine whether the orders are ordinary or not based on the requirements of the market in the first Member States and the previous relation between the wholesaler and the undertaking.[176]

5. Analysis

[173] Opinion of Advocate General Jacobs concerning Case C-53/03 delivered on 28 October 2004
[174] See, Opinion of Advocate General Jacobs concerning Case C-53/03, para 105
[175] Judgment of the Court of 16 September 2008.
Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE, Case C-468/06 to C-478/06. ECLI:
EU:C:2008:504. (hereinafter Case C-468/06, Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon)
[176] Regarding this case see Liberatore F, p. 354-355 as well as Case C-468/06, Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon

Parallel trade gives rise to a complicated and intricate situation that affects various actors and touches upon various fields of law. On the outset, it is about respecting the rights of parallel importers without diminishing the proprietors' right to prevent others from using or abusing their innovation. The ECJ has dealt with this issue for many years. As mentioned above parallel trade is an activity that is permitted according to Article 34-36 TFEU. These Articles set out one of the main principles of EU law, and that is free movement of goods and no quantitative restriction or measures of equal effect. It is also evident that the ECJ has used this principle as a guiding light in all its cases involving parallel trade and has established the principle of exhaustion. The principle of exhaustion basically implies that once a product has been placed on the market in any Member State within the EU the intellectual property rights are exhausted, i.e., the proprietor may not prevent further commercialization of his or her products by claiming intellectual property right infringement. This principle was further developed in the *Silhouette* case. In the *Silhouette* case the ECJ confirmed that products within the EU should move freely without being subjected to intellectual property right restrictions, once they have been placed in the EU market with the proprietor's consent. However, if the product has been placed outside the EU, the proprietor may rely on his or her intellectual property rights to prevent parallel trade.[177]

5.2 Consequences of parallel trade

There are various arguments in favour of parallel trade. The benefits of parallel trade are that original pharmaceutical drugs are made available at a lower cost. Furthermore, parallel trade also provides cost savings for social health insurance systems. It also generates competition and accelerates integration of the EU internal market.[178]

On the other hand, as Advocate General Jacobs highlighted in his Opinion there are some significant problems with parallel trade. Firstly, parallel trade does not necessarily cause any price reductions for the end consumers. In most cases the consumer pays a small amount of the pharmaceutical drugs prescribed to them. The

[177] Case C-355/96 Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH

[178] For further reading see European Association of Euro- Pharmaceutical Companies, What are the Benefits? Can be accessed at http://www.eaepc.org/parallel-distribution/who-gains/benefits,

remainder is covered by social health insurance. [179] Secondly parallel trade in pharmaceutical drugs creates difficulties for manufacturers and wholesalers to fulfill their obligation to supply the market with sufficient drugs to permanently satisfy the demand of the domestic market.[180]

A research study from 2004 showed that health insurance organizations only gain a modest direct saving from the conduct of parallel trade.[181] The same study showed that no direct benefit was accrued to patients, and access to medicines remained unaffected. In fact, the main beneficiaries of parallel trade are parallel importer themselves. Their direct maximum benefit exceeds those of health insurances considerably. The study also showed that very little evidence was found showing that parallel trade stimulates price competition and reduces price in the country of destination in the long run.[182]

As can be seen pharmaceutical companies are clearly threatened by the very existence of parallel trade.[183] They view parallel trade as the result of a fundamentally flawed market where drugs are controlled directly in low price countries and indirectly in high price countries. However, these price differentials do not have much to do with a natural demand but more to do with interference by the government of Member States causing distortions in the market.[184] The Commission on the other hand has had a positive attitude towards parallel trade. It regards parallel trade as an important driving force for market integration and the establishment of a single market.[185] Parallel trade causes a downward pressure on the prices in high priced markets and serves as an important tool for effective competition.[186]

---

[179] Regarding this paragraph see, Grigoriadis L, *The Application of EU Competition Law in the Pharmaceutical Sector: The Case of Parallel Trade,* European Business Law Review, Vol, 25, No. 1 2014 p. 146-147
[180] Regarding this paragraph see Grigoriadis L p. 146-148
[181] Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry & Gemmill, Marin, The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis, Special Research Paper, LSE Health and Social Care, London School of Economics and Political Science, London, January, 2004, p.15
[182] Kanavos, et. All. P.15
[183] See for example Case C-468/06, Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon, para 70, as well as Hunter R, p. 19
[184] See Hunter's R, reasoning p. 19
[185] Hunter R, p. 24
[186] Hunter R, p. 25

As can be seen the ECJ has moved further towards limiting the proprietor's rights in favor for parallel importers. This has put a lot of pharmaceutical manufacturers in a difficult position. In the *Centrafarm v Sterling* case and the *Consten & Grundig* case the ECJ claimed that derogations to the principle of free movement only applies to the "specific subject matter" and the "essential function" of the intellectual property right. For example, the use of an intellectual property as a tool to divide the market is not part of the essential function of the intellectual property right.[187] The ECJ has distinguished between having an intellectual property right and using it. However, one can question whether there is a point in having an intellectual property right if one is unable to use it to prevent others from exploiting your product.

It comes as no surprise that the ECJ has tried to chip away the protection that intellectual property rights owners enjoy in favor of parallel trade. This is after all is in line with the EU's objective of establishing an internal market and abolishing restrictions to free trade. However, one must not negate the fact that intellectual property rights serve an important dual purpose. They not only provide protection for the intellectual property rights owner they also encourage innovation and the production of new inventions by providing a safety net for the proprietor.[188] Having this protection threatened discourages manufacturers to invest in new inventions. This problem affects the health care and pharmaceutical sector to a very great extent. Member State not only have a responsibility to make sure medical supplies are available in the country[189] but also that these medicinal products are affordable. However, it is not the manufacturing pharmaceutical companies that determine the prices of medicinal products. This task is bestowed upon the government of Member States and based on the countries health insurance policies and demands. Furthermore, government authorities also set out regulatory requirements that indirectly affect the prices of medicinal products on a national level.[190] Lastly, parallel

[187] See for example Case C-56/64, Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community
[188] See Bernitz U, et. All. 2017, p. 7
[189] See Article 168 TFEU
[190] Feros A, *Free movement of pharmaceuticals within the EU - should rights be exhausted regionally?*, European Intellectual Property Review 2010, p. 497

importation not only offers reduced prices for medicinal products they also theoretically force national manufacturers to reduce their prices.

The situation gets even more complicated as there is also a desire to ensure that pharmaceutical companies are adequately rewarded for their innovation. One must always keep in mind that research is highly expensive, and it might take years before a research project leads to a result. The estimated cost of research and development of a new chemical or biological entity was 1, 926 million Euros in 2016. [191] In the pharmaceutical sector the financial risk is exceptionally high during the clinical trials and a large percentage of the research and development is financed by the pharmaceutical companies themselves.[192] Only around one or two out of every 10,000 synthesized substances will successfully complete all stages of development required for a medicine to become marketable.[193] One could argue that since there is always a constant need for new medicinal drugs, and the innovation, research and development of new drugs will be at risk if intellectual property rights owners are not promised proper protection.

5.3 Pharmaceutical Companies' Ability to Restrict Parallel Trade

Since pharmaceutical companies have not been capable of protecting their inventions and trademarks through intellectual property rights, focus has been shifted towards restricting parallel importation through competitive measures. As a result, in recent years the ECJ has faced an increase of cases involving competition law. In the early 1990s the ECJ dealt with agreements restricting trade under Article 101 TFEU.

The *GlaxoSmithKline* case of 1998 is an especially notable case as the court concluded that adopting two different pricing schemes for pharmaceutical drugs sold on the domestic market and products intended for export is a restriction to trade by object under article 101 TFEU. However, the ECJ also stated that this system could fall under Article 101(3) TFEU and enjoy exemption.[194]

---

[191] *DiMasi J. A, Grabowski H.G, Hansen R.W, Innovation in the Pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics, 47 (2016), p. 20–33*

[192] Nazerali JS, *Parallel imports of pharmaceuticals - a prescription for success or a free market overdose?* European Competition Law Review 1998, Sweet & Maxwell and its Contributors

[193] European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry in Figures, Key Data 2017, p. 6

[194] Case C-501/06, GlaxoSmithkline Services Unlimited v Commission

One can conclude from the *GlaxoSmithKline* case that the ECJ clearly recognizes pharmaceutical companies' rights and the negative consequences of parallel importation. In the *GlaxoSmithKline* case the ECJ responded to this by opening the door for a possible exemption under Article 101(3) TFEU for adopting two different pricing schemes for wholesalers planning on exporting goods. This is clearly different from the ECJ's past very-welcoming approach to parallel trade.[195]

The ECJ continued this line of reasoning in the *Bayer/Adalat* case. In the *Bayer/Adalat* case the ECJ concluded that a pharmaceutical manufacturer can adopt a supply quota system that limits the amount of pharmaceutical drugs to wholesalers as long as there is no consensus between the wholesaler and the pharmaceutical manufacturer. The ECJ also stated that this behavior is permitted even if it means certain restrictions on competition and affect trade between Member States.[196] Although the wording is rather vague the ruling suggests that pharmaceutical companies can prevent parallel importation by estimating how much the demand is for the domestic market and adopt supply quotas that covers just above the demand. At the end of the day it is about proving whether consensus lies between the pharmaceutical company and its wholesaler, and one could argue that this opens up the possibility for pharmaceutical companies to prevent parallel trade greatly. The *Bayer/Adalat* case has further opened up the possibility for inventors to protect their innovation and inventions through competitive measures without breaching Article 101 TFEU.

However, one could question whether the possibility for pharmaceutical companies in a non-dominant position have actually improved in practice. One must still keep in mind that estimating the demands for pharmaceutical drugs in the domestic market is difficult and requires a lot of accuracy. Pharmaceutical companies do not want to risk supplying too little drugs for the domestic market but supplying above the demand of the domestic market could lead to parallel trade. Estimating the volume of supply needed for the domestic market depends on the demand and the demand could change

[195] Compare for example, Case C-56/64, Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community.
[196] See Liberatore F, p. 353

over time. Furthermore, one could also criticize the ECJ's vagueness in these rulings as the ECJ has stated that adopting a dual pricing system is a restriction to trade by object under Article 101 TFEU, but could possibly enjoy exemption under Article 101(3) TFEU. However, the ECJ has not specified under what circumstances a pharmaceutical company's dual pricing system can be exempted. One could argue that in practice it is still very risky for pharmaceutical companies to adopt dual pricing systems, as the ECJ might find the behavior a restriction to trade under Article 101 TFEU.

The situation is even trickier when it comes to Article 102 TFEU and the abuse of dominant position and recently cases involving Article102 TFEU have become more frequent. In the *Syfait 2 case* the ECJ concluded that restricting the supply of goods by a dominant company, solely for the purpose of safeguarding its commercial interests is considered an abuse of dominant position. The ECJ still gave pharmaceutical companies a lifeline by claiming that manufacturers may refuse orders that are out of the ordinary.[197] The ECJ went on further and stated that two factors must be considered; the size of the order in relation to the requirement of the Market and the past business relationship between the pharmaceutical company and the wholesaler. Although the ECJ presented these guidelines it did not clarify what is meant by out of the ordinary and left it to the national courts to determine such matters. This ruling opens up a new set of questions such as do pharmaceutical companies need to apply a safety margin? What if the size of the order in relation to the requirements of the market are out of the ordinary, but not in relation to past orders between the wholesaler and the pharmaceutical company.[198] Once again it seems that the ECJ is trying to open the possibility for pharmaceutical companies to be able to restrict parallel trade in order to safeguard their rights and prevent the loss of revenue, for pharmaceutical companies. However, the question is whether these judgements are enough to safeguard the interests of pharmaceutical companies.

[197] See Case C-468/06, Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon
[198] NautaDutilh Newsletter, Syfait II, Newsflash Lifesciences, published in Lexology 2008.

5.4 Other solutions

It is rather unfortunate that no clear answers have been given by the ECJ when it comes to restricting parallel trade. On the other hand, it is quite evident that the ECJ is trying to strike a balance between the parallel importers rights and the rights of the pharmaceutical manufacturers, while still upholding its principle of free movement of goods and its aim to have a strong and growing health sector in the EU. There have also been other solutions discussed amongst scholars on how to handle this multifaceted area.

One solution as Hunter suggests, is a pan European pricing system. At the moment, national health policies of the Member States are the main actors determining the prices of pharmaceutical drugs. Hence a harmonized European pricing system would put an end to the price discrepancies of medicinal products between Member States and limit the threat of parallel trade. However, such a system would probably lead to price increases for those in the poorer parts of the EU, and pharmaceutical companies in wealthier states might not be able to set higher prices for their drugs either. Hence this system would probably never be accepted. [199]

Another suggestion is to offer a stronger protection for pharmaceutical drugs within for example the first 5 years of the grant of the patent. During this time, parallel import would be prohibited. After this period, the patent protection would decrease successively. However, having a strong protection of intellectual property rights could have negative consequences on competition as well as the free movement of goods.[200]

Another option could be to extend the period in which one could enjoy patent protection. This would address the issue of the need to earn a monopoly profit to pay for future investments. However, this is also an unlikely scenario as the EU is part of the WTO. The TRIPS agreement, which all the WTO members have signed, only allows 20 years of patent protection. It is unlikely that the other Members of the WTO would allow such an extension.[201]Furthermore it would also cause an incoherency between the internal and external markets of the EU.

[199] Regarding this paragraph see Hunter R, p. 68
[200] Regarding this paragraph seeHunter R, p. 68-69
[201] Regarding this reasoning see further, Hunter R, p. 69

The ECJ could even choose to not apply the regional exhaustion principle and consequently prohibit parallel trade with pharmaceutical drugs. After all, the doctrine of stare decisis[202] is not applied in the European Courts and theoretically the ECJ is not bound by its previous case law. However, changing its case law and legislation could cause inconsistencies between primary and secondary law. An incoherent application of law in the field of internal market, competition law, and intellectual property law could also occur. This would probably pose a threat to the establishment of a well-functioning single market.

One could argue that these somewhat drastic measures mentioned above will probably not be effective, as they would cause inconsistencies in the application of the principle of exhaustion and intellectual property protection as well as inconsistencies in the EU's internal and external policies. Furthermore, it could be said that these measures might not even be necessary in order to meet the objectives of the EU. Perhaps the most effective solution is for the ECJ to continue developing its case law in order to strike a balance that respects the interests of pharmaceutical companies as well as parallel traders. It could be argued that if pharmaceutical companies' rights are not respected, investment in new drug development and research will decrease. One could even argue that parallel trade could also force companies to reduce their prices[203], consequently reducing manufacturing costs and naturally, quality. The ECJ must be careful not to open Pandora's box by creating a "race to the bottom" of pharmaceutical drugs, simply because pharmaceutical companies are threatened by parallel traders and the principle of free movement of goods. If the concerns of the pharmaceutical sector are ignored the European pharmaceutical sector is at risk of being weakened.[204] In the end, it will be the consumers that will suffer and the health of the nations will be at stake.

[202] The doctrine implies that the Courts are bound by their past case law.
[203] Although as mentioned above studies have shown that parallel trade does not have a significant effect on price reduction, this is an important argument to highlight as pharmaceutical companies have expressed that parallel trade reduces pharamaceutical company's revenue.
[204] Compare Hunter R's reasoning p. 69

6. Conclusion

There is no doubt that the pharmaceutical sector is in a compromising position. The free movement provisions are chipping away manufacturers intellectual property rights, while competition rules are also applicable, hindering measures that distort competition. It comes as no surprise that he ECJ is seeing an increase of cases dealing with pharmaceutical companies taking measures that prevent parallel trade that affect competition law. At the moment, the ECJ and the Commission still seem to have a pro parallel trade view. However various arguments have shown that parallel trade has a negative impact on competition and reduce pharmaceutical companies' ability to invest in research and development. As a result, the ECJ has shown signs that suggest that the concerns of the pharmaceutical industry are not being ignored. When it comes to Article 101 TFEU, the ECJ seems to be opening the possibilities for pharmaceutical companies in a non-dominant position to restrict parallel trade. The ECJ has concluded that having a dual pricing scheme and charging different prices for domestic goods and goods intended for export, could be considered an exemption under Article 101(3) TFEU. This shift in view was also demonstrated in the *Bayer/Adalat* case. In the said case the ECJ concluded that restricting supplies to wholesalers in order to prevent parallel trade is permitted as long as there is no consensus between the pharmaceutical company and the wholesaler. At the end of the day it is about proving whether consensus lies between the pharmaceutical company and its wholesaler, and one could argue that this opens up the possibility for pharmaceutical companies to prevent parallel trade greatly. However, one must also consider that it is difficult to determine the volume of supplies required to fulfill the demands of the domestic market, and pharmaceutical companies must be very careful when restricting their supplies, as they might risk not supplying enough or even too much that parallel trade is still possible. Consequently, it remains to be seen whether pharmaceutical companies will be able to protect their interests in practice.

As for the possibility for pharmaceutical companies in a dominant position to prevent parallel trade without breaching Article 102 TFEU the situation looks different.
In *Syfait 2* the ECJ stated that restricting supply to wholesalers as a dominant company is an abuse of dominant position in the market under Article 102 TFEU. However, if the orders by the wholesalers are "out of the ordinary" the dominant

pharmaceutical company can refuse to supply. Unfortunately, the ECJ did not clarify what is meant by “out of the ordinary”. Instead the ECJ stated that the size of the order in relation to the demand of the market and past relation business of the pharmaceutical company and wholesaler has to be considered. This ruling, although it is has not completely ignored the interests of pharmaceutical companies, has left pharmaceutical companies in limbo, as they are unsure what are orders are considered out of the ordinary and what actions are considered abuse of dominant position precisely. It is safe to say that pharmaceutical companies in a dominant position are in a much more difficult position when it comes to preventing parallel trade than companies in a non-dominant position in the market. To summarize one can concluded that the ECJ is recognizing the concerns of the pharmaceutical companies and the negative effects of parallel trade in terms of research and development and effective competition. The ECJ has showed glimpses of wanting to create a proportionate balance between the interest of parallel traders and upholding the principle of free movement and protecting the interest of pharmaceutical companies ensuring that a coherent functioning system is established. Whether these efforts by the ECJ to open up the possibilities for pharmaceutical companies to protect their revenue and invest in future research and development is sufficient remains to be seen. One thing is for sure, if the needs of the pharmaceutical companies are not sufficiently met the health sector will be at risk of deteriorating. In the end, the health of the citizens will be at stake and ultimately they will be the ones that have to pay the price of a dysfunctional European pharmaceutical market.

11. Bibliography

11.1 Legal Instruments

Charter of Fundamental Rights of the European Union, 2012 O.J. C 326/391.

Consolidated Version of the Treaty on European Union, 2012 O.J. C 326/13.

Consolidated Version of the Treaty on the Functioning of the European Union, 2012 O.J. C 326/47.

United Nations, *Vienna Convention on the Law of Treaties*, 23 May 1969, United Nations, Treaty Series, vol. 1155, p. 331

Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark.

Regulation (EU) No 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices (Text with EEA relevance)

Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015

Council Directive No 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks.

Directive 2005/29/EC of The European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market 2005 O.J. L 149/22

Directive 2006/114/Ec Of The European Parliament And Of The Council of 12 December 2006, concerning misleading and comparative advertising 2006 O.J. L 376/21

Directive (EU) No. 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks

11.2 Litterature

Armengod Héctor, Baudenbacher Laura Melusine,The Repackaging of Pharmaceutical Products and Parallel Trade in the EU, Raj Pharma Legal feature, December 2009, p. 783

Aile Silvija, *Parallel Trade in Pharmaceuticals: Reconsidering the Underlying European Community Policies, Commentary on the Opinion of AG FrancisJacobs in*

Case C-53103 Bayer/Adalat, European Journal of Law Reform. Vol. VII, no. 3/4, Eleven International Publishing 2006

Barnard Catherine, *The substantive law of the EU: the four freedoms*, 5 ed., Oxford University Press, Oxford, 2016

Bernitz Ulf och Kjellgren Anders, *Europarättens grunder*, 5th Ed. Norstedts juridik, Stockholm 2014

Bernitz, Ulf, *Immaterialrätt och otillbörlig konkurrens: upphovsrätt, patent, mönster, varumärken, namn, firma, otillbörlig konkurrens*, 14 ed., Jure, Stockholm, 2017.

Braun David, Ritter Lennart, *European Competition Law: A Practitioner's Guide*, Kluwer law International (Third Edition), 2004

Commission Notice on the definition of relevant market for the purposes of Community competition law (97/C 372/03)

Europeiska kommissionen. Generaldirektoratet för näringsliv, *Fri rörlighet för varor: handledning för tillämpningen av fördragets bestämmelser om fri rörlighet för varor*, Europeiska unionens publikationsbyrå, doi:10.2769/30084
Luxemburg, 2010

Feros Anna , *Free movement of pharmaceuticals within the EU - should rights be exhausted regionally?*, European Intellectual Property Review 2010

Gold Michael A, *European Patent Law and Exhaustion Principle*, University of Chicago Legal Forum, Volume 1992 Issue 1, Article 19, 1992,

Granmar Claes, *Intellectual property rights and the single market*, European Intelletual Property Law, Rósen j, Edward, Elgar Publishing Limited, 2016, Ch. 2

Grigoriadis Lazaros , *The Application of EU Competition Law in the Pharmaceutical Sector: The Case of Parallel Trade*, European Business Law Review, Vol, 25, No. 1 2014

Hancher Leigh, *The pharmaceuticals market: parameters and pathways, Health Systems Governance in Europe: The Role of EU Law and Policy*, Cambridge University press Ch15, 2010.

Hartley Trevor C, The Foundations of European Union Law, Oxford University Press, 7th ed. 2010.

Hunter, Russel Graerne. *The pharmaceutical sector in the European union – Intellectual property rights, parallel trade and community competition law*. Institutet för Europeisk rätt vid Stockholms Universitet, Jure AB, Stockholm, 2001.

Jones Alison, *The Journey towards an effect-based approach under Article 101 TFEU- the case of hardcore restraints,* The Antitrust Bulletin: Vol. 55, No. 4/ Winter 2010

Jörgen Hettne och Ida Otken Eriksson (red.), *EU-rättslig metod: teori och genomslag i svensk rättstillämpning*, 2 uppl., Norstedts juridik, Stockholm, 2011

Kyle Margaret, Parallel trade in Pharmaceuticals: Firm Responses and Competition Policy, Fordham Competition Law Institute, 2009 Chapter 13.

Lenaerts Koen, Gutiérrez Fons José, *To Say What the Law of the EU is: Methods of Interpreation and the European Court of Justice*, EUI Working Papers AEL2013/9, Academy of European Law Distinguished Lectures of the Academy, 2013.

Liberatore Francesco, Restrictions on Parallel Trade of Pharmaceutical Products and EU Competition Law, EU Competition Law: Between Public and Private Enforcement, Kluwer International 2014 Chapter 17

Lidgard Hans Henrik, *Parallelhandel:konsumtion av immaterialrätt i Europa och USA*, Norstedts Juridik, 2002

Malaga M, The European Patent with Unitary Effect, - Incentive to Dominate, European intellectually property rights, 2014

Matthews Duncan and Viviana Munoz-Tellez. Parallel Trade: *A User's Guide. In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A
2007

Monaco Anna L, *The Role of Consent and Consumer Protection in Reconciling Articles 30 and 36 in Hag I and Hag II*, Fordham International Law Journal Volume 15, Issue 1, 1991, Article 6

Nazerali Julie S, *Parallel imports of pharmaceuticals - a prescription for success or a free market overdose?* European Competition Law Review 1998, Sweet & Maxwell and its Contributors

Nissen Morten, Van de Walle de Ghelcke Geoffroy, Vilarasau Melanie, *Competition Law in the Pharmaceutical Sector*, Guide to EU Pharmaceutical Regulatory Law, Editor, Shorthose Sally, 2010, Chapter 15, Kluwer Law International

Riksförsäkringsverket, *Parallellimporterade läkemedel: inte till vilket pris som helst*, Stockholm, 2000

Shorthose Sally, Smillie Mary, *Overview of European Pharmaceutical Regulatory Requirements, Guide to EU Pharmaceutical Regulatory Law*, Editor, Shorthose Sally, Chapter 1, 2010, Kluwer Law International.

Tumbridge Jason, *Syfait* 2: Restrictions on Parallel Trade Within the European Union, European Intellectual Property Review, 2009

Von Feld Ina, Neels Philipp, *Parallel Trade, Guide to EU Pharmaceutical Regulatory Law*,, Editor, Shorthose Sally, Chapter 14, 2010, Kluwer Law International

Whish Richard, Bailey David, *Competition Law*, Oxford University Press, 8th edition, 2015

Yarsky Joseph Kenneth, *Hastening Harmonization In European Union Patent Law Through A Preliminary Reference Power*, Boston College International & Comparative Law Review, Vol. 40, Issue 1, 2017

Pat Treacy Karima, Watson-Doig Noel, *What is Parallel Trade and How Does it Affect Pharma ?* Knekt 365 Law, CompLaw Blog, 1 Dec, 2016, https://knect365.com/complaw-blog/article/073ed81f-0d17-4c0e-a819-38ff60332dec/what-is-parallel-trade-and-how-does-it-affect-pharma
Retrieved 2 August 2017

Black S, Moor S, et. All, ECJ Ruling Dismisses AstraZeneca's appeal in Abuse of Dominance Case, Herbert Smith Freehills, Lexology, Blog, 6 Dec, 2012, http://www.lexology.com/library/detail.aspx?g=b36f264d-5978-4c18-ba0e-9d1cb559fc89)
Retrieved 8 June 2017

11.3 Cases

Judgment of the Court of 13 July 1966, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*. Case C-56/64, ECLI:EU:C:1966:41

Judgement of the Court of 8 June 1971 *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG*, Case C-78/70, ECLI:EU:C:1971:59

Judgment of the Court of 11 July 1974, *Procureur du Roi v Benoît and Gustave Dassonville,* Case C- 8-74, ECLI:EU:C:1974:82

Judgment of the Court of 31 October 1974 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*., Case C-15/74. ECLI:EU:C:1974:114

Judgment of the Court of 20 February 1979, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, Case C-120/7, ECLI:EU:C:1979:42

Judgment of the Court of 14 July 1981*, Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler*, Case 187/80, ECLI:EU:C:1981:180

Judgement of Court of 16 June 1987, *Commission v Italy*, Case C-118/85, ECLI:EU:C:1987:283

Judgment of the Court of 23 April 1991*, Klaus Höfner and Fritz Elser v Macrotron GmbH,* Case C-41/90, ECLI:EU:C:1991:161

Judgement of the Court of 18 February 1992,
Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland, Case C-30/90 ECLI:EU:C:1992:74

Judgment of the Court of 11 July 1996, *Bristol-Myers Squibb v Paranova A/S and C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S and Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S*, Cases C-427/93, C-429/93 , C-436/93, ECLI:EU:C:1996:282

Judgment of the Court of 16 July 1998, *Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH*, Case C-355/96, ECLI:EU:C:1998:374

Judgment of the Court of 20 November 2001*, Zino Davidoff SA v A & G Imports Ltd and Levi Strauss & Co. and Others v Tesco Stores Ltd and Others*, Cases C-414/99 to C-416/99 ECLI:EU:C:2001:617

Judgment of the Court (Full Court) of 6 January 2004. *Bundesverband der Arzneimittel-Importeure eV and Commission of the European Communities v Bayer AG*, C-2/01 P Case C-3/01 P, EU:C:2004:2

Judgment of the Court (Grand Chamber) of 31 May 2005
Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE, Case C-53/03, ECLI:EU:C:2005:333

Judgment of the Court (Grand Chamber) of 16 September 2008.
Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE, Cases C-468/06 to C-478/06. ECLI:
EU:C:2008:504.

Judgment of the Court of 6 October 2009, *GlaxoSmithKline Services Unlimited v Commission of the European Communities* and Commission of the European Communities v GlaxoSmithKline Services Unlimited and European Association of Euro Pharmaceutical Companies (EAEPC) v Commission of the European Communities and Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v Commission of the European Communities, Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, ECLI:EU:C:2009:610

Judgment of the Court of 19 January 2010 *Seda Kücükdeveci v Swedex GmbH & Co. KG*, Case C-555/07, ECLI:EU:C:2010:21

Judgment of the Court of 6 of December 2012, *AstraZeneca v Commission*, Case C-457/10 P, ECLI:EU:C:2012:770

11.4 Other

Black S, Moor S, et. All, ECJ Ruling Dismisses AstraZeneca's appeal in Abuse of Dominance Case, Herbert Smith Freehills, Lexology, Blog, 6 Dec, 2012, http://www.lexology.com/library/detail.aspx?g=b36f264d-5978-4c18-ba0e-9d1cb559fc89)
Retrieved 8 June 2017

European federation of Pharmaceutical Industries and Associations, The pharmaceutical industry in Figures, Key Data 2017

Fact Sheet on the European Union 2017, Sources and Scope of European Union Law,

JA kemp Briefing, Parallel Imports of Pharmaceutical Products in the European Union: When Can Goods be Re-packaged and Re-branded, 2014, http://jakemp.com/en/knowledge-centre/briefings/topical-briefings-2/parallel-imports-of-pharmaceutical-products-in-the-european-union-when-can-goods-be-re-packaged-and-re-branded

Joseph. A. DiMasi, Henry G. Grabowski, Ronald W.Hansen, Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics, 47 (2016), p. 20–33

NautaDutilh Newsletter, Syfait II, Newsflash Lifesciences, published in Lexology 2008, https://www.lexology.com/library/detail.aspx?g=ea6745d3-13ea-48e3-ace8-7d83fc399ad6
Retrieved 8 June 2017

Neruda Robert, Barinka Roman, Minárik Marián, *Parallel Imports in EU Law,* published in Lexology, 2015
https://www.lexology.com/library/detail.aspx?g=71bc5df8-766d-483d-96f0-ba8be5c60dc1
Retrieved 1 June 2017

Pat Treacy Karima, Watson-Doig Noel, *What is Parallel Trade and How Does it Affect Pharma ?* Knekt 365 Law, CompLaw Blog, 1 Dec, 2016, https://knect365.com/complaw-blog/article/073ed81f-0d17-4c0e-a819-38ff60332dec/what-is-parallel-trade-and-how-does-it-affect-pharma
Retrieved 2 August 2017