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Parallel Trade in Pharmaceuticals in the EU:  
*benefitting whom?*

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# Summary

The aim of this thesis is to investigate whether restrictions to parallel trade in the pharmaceutical industry, distorting the internal market, are treated differently by the Court of Justice compared to other sectors, on grounds of the specific characteristics of the pharmaceutical sector. For this purpose the focus is on restrictions deriving from dominant pharmaceutical companies' refusal to supply wholesalers engaged in parallel trade.

The second chapter presents a short overview of the specific regulatory framework for pharmaceuticals within EU law as well as the special characteristics of the pharmaceutical sector are analyzed.

In the third chapter there is a brief description of specific legal questions relating to parallel trade within the EU, with a special focus on how the rules on free movement of goods have been interpreted and applied in context with this sector, particularly in relation to regulatory barriers to trade and how IPRs (intellectual property rights) have been raised to impede parallel trade. The main competition law matters related to parallel trade in pharmaceuticals are also discussed shortly in this context.

The fourth chapter's focus is on EU competition law and refusal deal as an abuse of dominant position in general. Furthermore, the Court of Justice's approach to abusive conduct, aiming at restricting parallel trade, is discussed briefly. The fourth chapter is followed by a special analyzes on refusal to supply within the pharmaceutical sector in chapter five.

After investigating the law as it stands regarding refusal to supply within the pharmaceutical sector an attempt is made, in chapter six, to analyze how it affects the economic sphere. For this purpose the question of who actually benefits from parallel trade in pharmaceuticals is set forth.

The main findings of the thesis are that the Court of Justice has been keen on facilitating parallel trade within the pharmaceutical industry. Recent ruling on refusal to supply medicine to parallel traders gives the impression that the Court is unwilling to provide special treatment for the pharmaceutical industry on grounds of the industry's distinct characteristics. Instead, the Court of Justice has emphasized the importance of the functioning of the internal market and the free movement of goods, which is the cornerstone for parallel trade within the EU. However, although favoring the free movement of pharmaceutical products, it cannot be neglected that the Court of Justice is willing to give pharmaceutical companies some leeway to take actions to protect their commercial interests.

Although consumers are likely achieve some benefits from parallel trade, most of the profit from such trade will most likely end with wholesalers engaged in such trade. Contrary to this, the pharmaceutical undertakings – which have invested in the development of the pharmaceutical products at issue – do not gain from such trade. Reduced profits for pharmaceutical companies will probably affect the budget spent on innovation to the detriment of potential patients. Even more seriously, pharmaceutical companies can decide to withdraw their products from low price markets. That threat appears to be especially evident at the moment when low price Member States are continuing to cut prices on medicine.

# Abbreviations

<b>AG</b>	<b>Advocate General</b>
<b>CFI</b>	<b>Court of First Instance</b>
<b>EEA</b>	<b>European Economic Area</b>
<b>EFTA</b>	<b>European Free Trade Association</b>
<b>EMA</b>	<b>European Medicines Agency</b>
<b>EU</b>	<b>European Union</b>
<b>GSK</b>	<b>GlaxoSmithKline</b>
<b>IPR</b>	<b>Intellectual property right</b>
<b>R&amp;D</b>	<b>Research and development</b>
<b>TFEU</b>	<b>Treaty on the functioning of the European Union</b>

# 1 Introduction

## 1.1 Objective

One of the fundamental goals of European integration has been to create an internal market where goods, persons and capital can move freely between the Member States of the European Union (EU). The rules in the Treaty on the Functioning of the European Union (TFEU) that facilitate free movement aim at optimal allocation of resources; in theory, such allocation can be reached by allowing product factors to move where they are most valued and products to move where they are most favored by consumers.<sup>1</sup>

Although several steps have been taken to harmonize rules within the internal market, the prices of the same products still vary between different Member States. The reasons for this can be based on many independent factors, such as different importance of brand images, different frameworks for competition, exchange rate fluctuations, varying distribution costs, varying demand, and diverse regulatory and fiscal regimes.

The above mentioned differences have proved to be especially significant in relation to the heavily regulated industry of pharmaceutical products. Price differences within this sector have encouraged parallel trade in pharmaceuticals, where products from low price areas have been imported to high price areas within the EU.<sup>2</sup> Legal issues regarding the benefit of parallel trade have been debated for a long time, since this method of business has raised several significant questions regarding regulatory barriers to free movement of goods, exhaustion of intellectual property rights (IPRs), and competition law.

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<sup>1</sup> See Craig, Paul and Gráinne, de Búrca, *EU Law – Text, Cases and Material*, Oxford University Press, 2008, page 605.

<sup>2</sup> See e.g. Nguyen, Thanh Tu, Minissen, Timo and Groussot, Xavier, *The Rule of Reason under Article 82 EC After Sot Lelos kai Sia*, Social Science Research Network, 2009, page 22, available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1431010](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1431010). Visited on 5 July 2010.

In my thesis I want to investigate whether restrictions to parallel trade in the pharmaceutical industry, distorting the internal market, are treated differently by the Court of Justice compared to other sectors, on grounds of the specific characteristics of the pharmaceutical sector. For this purpose I will focus on restrictions deriving from a dominant pharmaceutical companies' refusal to supply wholesalers engaged in parallel trade. I will attempt to answer questions like whether such a refusal to supply is to be treated as an abuse of a dominant position under Article 102 TFEU and if so, under which circumstances? Furthermore, is the special nature of the pharmaceutical sector perhaps to be taken into consideration when considering business practices limiting parallel trade within this industry? Finally I will raise the question of who actually benefits from parallel trade in pharmaceuticals.

I think this subject is worth discussion at the moment since recent case law from the Court of Justice<sup>3</sup> sheds some light on how this legal matter is likely to be treated in the future while at the same time it leaves some questions unanswered on the matter. The newly adapted guidance on the Commission's enforcement priorities in applying Article 82 EC (now Article 102 TFEU) to abusive exclusionary conduct by dominant undertakings are also of an interest in this context.

## 1.2 Method and Material

The main method used in the thesis is the legal dogmatic method, aiming at establishing *de lege lata*. This includes analysing the regulatory framework surrounding the pharmaceutical industry within the EU. For this purpose I will introduce relevant provisions in the TFEU as well as secondary legislation and published documents from the Commission related to the matter. Furthermore, I will discuss relevant judicial doctrine deriving from the Commission and EU Courts on parallel trade within the pharmaceutical industry as well as doctrine concerning a dominant's company refusal to supply, both in general and with a special emphasis on case law concerning

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<sup>3</sup> See Joined Cases C-468/06-C-478/06 *Sot. Lelos kai Sia EE v GlaxoSmithline AEEV*, [2008] ECR I-7139.

pharmaceutical undertaking's refusal to supply. Apart from analyzing the applicable law within this field I will rely on material that has been published on the matter as a starting point for further discussion on the topic.

The above mentioned sources are necessary to be capable of making an attempt to state how EU law – concerning a pharmaceutical undertaking's refusal to supply – stands at present. After doing so I will endeavor to analyze the economic impact of the EU approach by using law and economics perspective. Hereby I mean that a focus will be on the economic impact of the current approach to parallel trade within the pharmaceutical industry. The aim of this is to answer the question of who benefits from parallel trade in pharmaceuticals and how it affects consumer welfare in a wide perspective, *i.e.* how it is likely to affect prices of medicines within the EEA and its effects on R&D (research and development) within the pharmaceutical sector.

### **1.3 Delimitations**

In this thesis it will be assumed that the reader has some general background knowledge within the field of EU competition law. Therefore the thesis will not go into detail about the general aspects concerning the definition of a dominant company and general aspects of abuse of a dominant position in EU law. At the same time there will not be a detailed discussion on the general rules underlying the principle of free movement of goods and there will be assumed that the reader is familiar with the general principles on the functioning of the internal market and how the free flow of products and product factors can be restricted.

The thesis is also limited to discussion of competition law issues relating to parallel trade in pharmaceuticals, *i.e.* intra brand competition in the pharmaceutical industry. The discussion on other abusive conducts within the pharmaceutical industry, *e.g.* relating to inter brand competition will not be dealt with unless necessary for the context of the main topic. Furthermore, other restrictions to parallel trade such as regulatory barriers and exhaustion of IPRs will only be touched upon briefly.

When discussing business practices limiting parallel trade, the focus will be on a dominant company's refusal to supply pharmaceuticals to wholesalers engaged in parallel trade. Other business practices distorting the internal market by limiting parallel trade in pharmaceuticals, such as the application of dual pricing policies, will not be dealt with in detail.

Although the discussion in this thesis sometimes refers to the Internal Market of the 27 EU Member States it shall be noted that the Internal Market of the EU and its competition rules have been extended to the EFTA States that are parties of the Agreement on the European Economic Area (*i.e.* Iceland, Norway and Lichtenstein). The same rules and principles apply to the European Economic Area (EEA) when it comes to parallel trade in pharmaceuticals and the discussion in this thesis applies therefore to the 30 Member states of the EEA. Importation of pharmaceuticals from outside the EEA will, however, not be discussed in the thesis.

Additionally it is worth mentioning that in this thesis I will refer to provisions in the Treaty on the Functioning of the European Union when the provisions are identical in substance to provisions in the EC Treaty, although the rulings analysed were given prior to the entering into force of the Treaty on the Functioning of the European Union. Furthermore, I will refer to the General Court instead of the Court of First Instance (CFI), although the rulings analysed were given prior to the entering into force of the Treaty on the Functioning of the European Union.

## **1.4 Disposition**

As to the structure of this thesis, the discussion from now on will be divided into five chapters. In chapter two, there will be a short overview of the specific regulatory framework for pharmaceuticals within EU law as well as the special characteristics of the pharmaceutical sector will be analyzed.

In the third chapter there will be a brief description of specific legal questions relating to parallel trade within the EU, with a special focus on how the rules on free movement of goods have been interpreted and applied in context with this sector, particularly in

relation to regulatory barriers to trade and how IPRs (intellectual property rights) have been raised to impede parallel trade. The main competition law matters related to parallel trade in pharmaceuticals will also be discussed shortly in this context. Although this research is focused on refusal to supply as a method of restricting parallel trade, I find it important for the context of the topic to discuss other methods of restricting parallel trade in pharmaceuticals briefly.

The fourth chapter's focus is on EU competition law and refusal to supply and license as an abuse of dominant position in general. Furthermore, the Court of Justice's approach to abusive conduct, aiming at restricting parallel trade, will be discussed briefly. The fourth chapter will be followed by a special analyzes on refusal to supply within the pharmaceutical sector in chapter five. In this chapter special focus will be on the Court of Justice's approach to parallel trade in pharmaceuticals as well as relevant opinions of Advocates Generals will receive a discussion. The focus of the discussion in chapter five will be on whether the pharmaceutical sector is treated differently from other sectors on grounds of its specific characteristics.

After investigating the law as it stands regarding refusal to supply in the pharmaceutical sector I will make an attempt to analyze how it affects the economic sphere in chapter six. For this purpose I will set forth the question of who actually benefits from parallel trade in pharmaceuticals, in the light of the relevant case law that has been dealt with in chapter five. This will be supported by discussion on relevant economic research conducted on the matter.

Finally, in chapter seven, the main conclusions of the thesis will be summarized.

# 2 EU law and the pharmaceutical industry

## 2.1 Competence of the EU within the Field of Public Health

When it comes to the field of public health, the EU has limited competences to set harmonizing measures and, according to Article 168 TFEU, the role of the EU in public health matters is merely to complement the measures taken by Member States. Furthermore, Article 168(7) TFEU states that EU action shall respect the responsibilities of the Member States for defining their health policy, and for organizing and delivering health services and medical care. The responsibilities of the Member States, under Article 168(7) TFEU include the management of health services and medical care and the allocation of their resources. As a result, single Member State's pricing and reimbursement policies and rules for pharmaceutical products are not harmonized but under national competence. It must, however, be kept in mind that when carrying out their responsibilities, Member States and pharmaceutical companies must respect EU Treaty provisions concerning competition and the Internal Market.

Although Article 168 TFEU gives the EU limited power to deal with public health matters, some important harmonizing measures have, however, been enacted under Article 114 TFEU, which is the main legislative source for harmonizing the internal market. The most important secondary legislation for the purpose of parallel trade in pharmaceuticals that has been adopted by the EU are Directives 2001/83/EC<sup>4</sup> on the Community code relating to medicinal products for human use, and Directive 89/105/EEC<sup>5</sup>, often referred to as the Transparency Directive. The content of those Directives will be dealt with further in chapters 2.2-2.5.

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<sup>4</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, [2001] OJ L 311/67.

<sup>5</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, [1989] OJ L 40/8.

## **2.2 Medicinal Products**

The concept medicinal product is defined in Article 1(2) in Directive 2001/83 as any substance or combination of substances presented for treating or preventing diseases in human beings. When referring to pharmaceuticals in the thesis I will base the definition of the concept on the definition of medicinal products as defined in Article 1(2) in Directive 2001/83.

## **2.3 Marketing Authorization**

From 1965, the EU has been developing a harmonized legislative framework for pharmaceutical products based on common authorization procedure. According to Article 6.1 of Directive 2001/83 no medicinal product may be placed on the market of a Member State without marketing authorization. The primary purpose of this requirement is to safeguard public health.

Directive 2001/83 sets down two procedures for marketing authorization for medicinal products for human use, a decentralized procedure where single Member States grant market authorization and a centralized procedure, administrated by the European Medicines Agency (EMA). All medicine that is to be put on the market in the EU must have been granted authorization in accordance with the Directive.

The decentralized procedure for marketing authorization was first introduced in 1965. It creates a mutual recognition procedure for certain pharmaceutical products. When a medicinal product achieves authorization in one Member State, the authorization should also be recognized and respected in other Member States.

In 1995 a centralized authorization procedure was introduced with the creation of EMA. The application of the centralized procedure can, in some cases, be mandatory for the pharmaceutical company. That is, however, not always the case since it is

sometimes optional for pharmaceutical companies to apply for a centralized authorization, for instance when the product contains a new active substance and if innovation role is great.

The above mentioned procedures, aim at creating an internal market for pharmaceuticals where medicinal products from one country can be exported to other countries within the European Economic Area without EEA States being able to set further regulatory restrictions on imported products.

## **2.4 Obligation to Supply Medicines**

As a general rule, manufacturers of goods on a free market can decide the quantity of the goods they want to supply on a market. The state does normally not have any role in when it comes to deciding how much should be produced of certain goods from private parties. A clear exemption from this general rule is the pharmaceutical sector which has certain public service obligations when it comes to supply of pharmaceutical products.

Those public service obligations are defined in Article 1 (18) of Directive 2001/83/EC as “the obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.”

According to Directive 2001/83 pharmaceutical companies are under an obligation to ensure supply of medicinal products. In Article 81(2), it is stated that the holder of a marketing authorization and relevant distributors, have the obligation to ensure appropriate and continued supplies of the authorized medicinal product to pharmacies and persons authorized to supply medicinal products so that the needs of patients in the Member State are covered. Therefore the company, subject to market authorization, has an important legal obligation to prevent the occurrence of shortage of the

authorized product in a Member State which limits its freedom to plan its business solely in accordance with its own interests.

## 2.5 Regulated Prices

EU legislation does not by any mean aim at harmonizing the pricing of medicinal products between Member States. This can be read out of Article 168(7) TFEU where it is stated that Member States are responsible for the management of their health services and medical care and the allocation of their resources. This is also clearly stated in Article 4(3) of Directive 2001/83 where it is stated that the Directive does not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance scheme. Actions aiming at harmonizing prices of medicines have not proved to be successful.<sup>6</sup>

EU legislation is, however, not entirely silent about price decisions and according to the Transparency Directive 89/105/EC, Member States shall ensure that national price and reimbursement decisions for medicinal products are taken in a transparent, non-discriminatory way and within specific time limits.

As a consequence of Member States' power to control prices of medicinal products in their territories there exist great differences in prices of medicinal products for human use in the EU, mainly due to different policies for pricing and reimbursement.<sup>7</sup> This, in turn, effects in a fragmented market for pharmaceuticals within the EEA.

Most Member States have fixed prices, where a regulatory authority has the role to fix the price, sometimes through negotiation with the pharmaceutical company that

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<sup>6</sup> Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: "A stronger European-based Pharmaceutical Industry for the benefit of the Patient – A Call for Action" Brussels, 1 June 2003, COM(2003) 383 final, page 14, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2003:0383:FIN:EN:PDF>. Visited on 5 July 2010.

<sup>7</sup> See e.g. Report of the OECD, *Pharmaceutical Pricing Policies in a Global Market*, 2008, OECD, Paris.

produces the product. This is for instance the case in Sweden where the manufacturer suggests a price for a product to the relevant authority. If the Authority accepts the price the manufacturer cannot subsequently raise the price without the consent of authorities. Other countries, like for instance the UK and Germany, do not have any governmental interference with the pricing of pharmaceuticals and therefore the price is market based. There may, however, be some indirect price control like in the UK, where profits for pharmaceutical companies are limited. The different price mechanisms between Member States, combined with differences in GDP, effect in great price differences between Member States, which make the business of parallel trade desirable.<sup>8</sup> In countries where prices for medicines are relatively high governments have even taken actions to promote parallel trade. This applies, for instance, to Denmark, Germany, the Netherlands, Sweden and the United Kingdom, where the dispensing of parallel imported pharmaceuticals has been promoted.<sup>9</sup> Contrary to this, the so called low price Member States like Spain, France and Greece are concerned about the effect that such trade has on their pharmaceutical markets, and have in some cases introduced measures to account for the extent of parallel export from their territory.<sup>10</sup>

The Court of Justice stated in *Roussel Laboratoria BV and Ors v État Néerlandais*<sup>11</sup> that price-setting in the pharmaceutical market does not violate EU law as such if it does not discriminate between domestic products and imported products.<sup>12</sup> The Court of Justice looks to the effect of pricing system and if price on domestic products and imported products is set according to the same criteria, such a measure can be considered to be a measure having an equivalent effect to quantitative restriction if it

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<sup>8</sup> See Kingston, S., *Joined cases C-468/06 to C-478/06, Sot. Lelos kai sia EE, Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Pronotion, formerly Glaxowellcome AEVE, Judgment of the Grand Chamber of the Court of Justice of 16 September 2008*, CMLR, 2009 (46), pages 684-685.

<sup>9</sup> Kanavos, Costa-i-Font, Merkur and Gemmil, *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholders Analysis*, Special Research Paper of the London School of Economics and Political Science, 2004, page 62.

<sup>10</sup> *Ibid*, page 85.

<sup>11</sup> Case C-181/82 *Roussel Laboratoria BV and Ors v État Néerlandais*, [1983] ECR-3849.

<sup>12</sup> *Ibid*, paras. 17-19.

the price is fixed at such a rate that the sale of imported products is either impossible or more difficult than that of domestic products.<sup>13</sup>

## 2.6 Innovation

An important characteristic of the pharmaceutical industry is its reliance on innovation for the development of new products. The development of a new medicinal product takes long time and the cost invested in R&D is very high for pharmaceutical companies. Additionally, only a small fraction of the products invested in, ever manage to enter the market.<sup>14</sup> As a consequence of pharmaceutical companies' high investment cost in innovation, the industry relies on IPRs to protect their commercial interests when new products are marketed mainly by patents and trademarks. In context with competition law, this characteristic of the pharmaceutical sector has influence, since the granting of patents confers temporary monopoly upon the patent holder. In turn this is especially important within the field of parallel trade, since during the term when a product is patented, the only possibility for competition is through intra brand competition.<sup>15</sup>

The importance of innovation and effective protection of IPRs has proved to be a priority goal on an EU level.<sup>16</sup> Naturally however, a balance must be struck between the interests of investment in R&D and protection of IPRs and encouraging optimal competition. If too much emphasis is placed on encouraging R&D and protecting IPRs it will lead to the risk of reduced price competition, likely to result in higher consumer prices. At the same time, if too much emphasis is on protecting optimal competition there will be a risk of lack in incentives for innovation in the long term or the risk of

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<sup>13</sup> See Case C-67/75 *Tasca*, [1976] ECR 291, Joined Cases C-88-90/75 *Sadam*, [1976] ECR 323, Case C-82/77 *Van Tiggele*, [1978] ECR 25, Joined Cases C-16-20/79 *Danis*, [1979] ECR 3277.

<sup>14</sup> See e.g. Di Masi, Joseph A., *et.al.*, *The price of innovation: new estimates of drug development costs*, *Journal of Health Economics*, 22(2003), pages 151-185.

<sup>15</sup> See e.g. *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE*, cited *supra* note 3, para 64.

<sup>16</sup> See e.g. Final Report of the Sector Inquiry into Pharmaceuticals pursuant to Article 17 of Regulation (EC) No 1/2003, 8 July 2009, page 1. Available at: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf). Visited on 5 July 2010.

having dominant undertakings refraining from placing new products on the markets in lower price Member States.<sup>17</sup> Those conflicting interests will receive a more in depth analysis later in the thesis, in chapters 5 and 6.

## 2.7 Stakeholders

The question of who benefits from parallel trade in pharmaceuticals is a controversial one, and it is not easy to balance the interests at stake. The main stakeholders are pharmaceutical companies, wholesalers participating in parallel trade, consumers and Member States, since they often bear substantial part of the cost of pharmaceuticals.

The main arguments carried forward by those in favor of parallel trade in pharmaceuticals is that it will lead to intra brand competition, which will, in the long run, lead to lower prices in medicine and therefore benefit consumers.<sup>18</sup> In support of these arguments, some studies have shown that pharmaceuticals in countries where parallel trade is prohibited are in general more expensive than within the EEA, where such trade has been facilitated.<sup>19</sup>

Apart from the parallel wholesalers, who have obvious interests from parallel trade in pharmaceuticals, high price Member States in the EU have also taken actions to encourage such trade. This applies, for instance, to Denmark, Germany, the Netherlands, Sweden and the United Kingdom, where the dispensing of parallel imported pharmaceuticals has been promoted.<sup>20</sup>

Another strong argument for facilitating parallel trade in pharmaceuticals is that such trade is in line with the fundamental principle of EU law, that goods shall be capable of moving between Member States of the EU without restrictions.<sup>21</sup>

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<sup>17</sup> See Kingston, S., cited *supra* note 8, page 699.

<sup>18</sup> See Nguyen, Thanh Tu *et. al.*, cited *supra* note 2, page 24.

<sup>19</sup> See e.g. Kyle, Margaret K., *Strategic Responses to Parallel Trade*, 2007, page 2. Available at: [http://w4.stern.nyu.edu/emplibary/Strategic\\_Responses\\_to\\_Parallel\\_Trade.pdf](http://w4.stern.nyu.edu/emplibary/Strategic_Responses_to_Parallel_Trade.pdf). Visited on 5 July 2010.

<sup>20</sup> See Kanavos, Costa-i-Font, *et.al.*, cited *supra* note 9, page 62.

<sup>21</sup> See e.g. Joined Cases C-267-268/95 *Merck & Co Inc v Primecrown Ltd*, [1996] ECR I-6285, para 47.

Pharmaceutical undertakings have attempted to take several actions to impede parallel trade in pharmaceuticals, and their arguments against such method of trade have been manifold.

Firstly, pharmaceutical companies have argued that parallel trade should, under certain circumstances, be limited on grounds of public health reasons.<sup>22</sup>

Secondly, they have argued that the general logic behind protecting intra brand competition within the field of pharmaceuticals does not function, due to the intervention of public authorities in the pricing mechanism of such products, which obstructs normal competition conditions.<sup>23</sup>

Thirdly, they have argued that producers of medicine are subject to precise obligations to distribute their products in all countries where they are authorized, while parallel exporters are free to shift their activities from one product or market to another, which can lead to shortages in some exporting Member States.<sup>24</sup>

Fourthly, they have pointed out that parallel trade will reduce the profits for pharmaceutical companies and therefore decrease investment in R&D activities, as well as the pharmaceutical companies could have interest in delaying the launch of new products in low price Member States to protect their interests.<sup>25</sup>

Additionally, pharmaceutical companies have contended that parallel trade will not provide genuine benefit to consumers, since the profit will end in the pocket of the parallel traders, not the consumers.<sup>26</sup>

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<sup>22</sup> See, e.g. C-172/2000 *Ferring Arzneimittel GmbH v Eurim-Pharm Arzneimittel GmbH*, [2002] ECR I-689, paras. 27-29.

<sup>23</sup> See e.g. *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE*, cited *supra* note 3, para 41.

<sup>24</sup> *Ibid*, para 43.

<sup>25</sup> *Ibid*, para 44.

<sup>26</sup> *Ibid*, para 45.

Pharmaceutical companies are not the only parties that have interests in impeding parallel trade in pharmaceuticals. While high price Member States consider themselves to benefit from parallel trade, the so called low price Member States, like Spain, France and Greece are concerned with the adverse effect that such trade can have on their pharmaceutical markets. In some cases those countries have introduced measures to account for the extent of parallel export from their territory.<sup>27</sup>

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<sup>27</sup> See Kanavos, Costa-i-Font, *et.al.*, cited *supra* note 9, page 85.

# 3 Parallel Trade

## 3.1 Parallel Trade within the EU

Parallel trade refers to the activity of purchasing goods in one country and re-selling them in another country where the price of the product is higher, without the consent of the local owner of the IPR in the country of purchasing. By doing so, the parallel trader can make profit by the price difference of the product at issue. This way of making business has also been referred to as grey market trade.

Any analysis on parallel trade in goods must start with an introduction to the general rule on free movement of goods, stipulated in Article 34 TFEU, where quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. The prohibition is subject to Article 36 TFEU, under which restrictions *inter alia* on grounds of protection of health and life of humans, animals or plants, and the protection of industrial and commercial property, can be justified if they do not constitute means of arbitrary discrimination or a disguised restriction on trade.

The Court of Justice gave its first landmark ruling facilitating parallel trade already in 1966, in *Consten and Grundig*<sup>28</sup>. In that case the Court declared that an agreement whereby German electronics manufacturer, Grundig, granted absolute territorial protection in France to Consten, its exclusive distributor, infringed Article 101(1) TFEU. Ever since the *Consten and Grundig* ruling, the Commission's and the EU Court's approach to restrictions designated to impede parallel trade has been hostile. Their condemnation of such restrictions has been motivated by three closely linked objectives, namely to promote intra brand competition, the achievement of market integration within the Union and the protection of the parallel trader.<sup>29</sup>

Subsequent chapters (3.2-3.4) will aim at analyzing in more detail the activity of parallel trade in the pharmaceutical sector, and attempts to restrict such trade.

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<sup>28</sup> See Cases C-56 and 58/64 *Consten and Grundig v. Commission*, [1966] ECR-299.

<sup>29</sup> Van Bael & Bells, *Competition Law of the European Community*, Kluwer Law International, 2005, page 244.

## 3.2 Parallel Trade in Pharmaceuticals

The fact that prices for pharmaceutical products vary greatly between Member States in the EU has made this sector particularly attractive for the business of parallel trade. In practice, pharmaceutical companies have tried to hinder such trade through many means, such as by invoking regulatory barriers to parallel imports or by claiming that IPRs can hamper such trade. Pharmaceutical companies have also taken actions against parallel importers by refusing to supply them or through dual pricing policies.

### 3.2.1 Regulatory Barriers

As stated in chapter 2.3, the law in the EU concerning authorization for medicinal products has been harmonized. The Court of Justice has, however, had to deal with regulatory barriers to parallel trade in pharmaceuticals on ground of restrictions related to such authorization. Those cases have concerned attempts by holders of marketing authorization to try to hamper import of medicinal products from other countries in the EU mainly by raising three defenses; first, by claiming that the authorized product and the imported product are not in every aspect the same, second, by stating that the link between the holder of marketing authorization in the country of import and the parallel importer is insufficient, and finally, by withdrawing the marketing authorization for the local product to impede imported products' access to the market.<sup>30</sup> These defenses have not proved to be successful for the purpose of impeding parallel trade, and the practicality of them has decreased since 1995 when it became possible or even obligatory under some circumstances to apply for a central market authorization through EMEA for new medicinal products.<sup>31</sup>

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<sup>30</sup> See. e.g. Cases C-104/75 *Officier van Justitie v Adriann de Peijper*, [1976] ECR 613, C-201/94 *R v MCA ex parte Smith & Nephew Pharmaceuticals Ltd and Primecrown Ltd v The Medicines Control Agency*, [1996] ECR I-5819, C-94/98 *R v Medicines Control Agency ex parte Rhone Poulenc Rorer*, [1999] ECR-I 8789, C-112/02 *Kolpharma GmbH v Germany*, [2004], C-172/2000 *Ferring Arzneimittel GmbH v Eurim-Pharm Arzneimittel GmbH*, [2002] ECR I-689, C-15/01 *Parmanova Laekemedel AB and others v Lakemedelsverket*, [2003] ECR I-4175.

<sup>31</sup> See. Cook, Trevor, *Pharmaceuticals Biotechnology and the Law*, LexisNexis, 2009, pages 383-391.

### 3.2.2 Exhaustion of IPRs

Pharmaceutical companies have, in their attempts to limit parallel trade in pharmaceuticals, invoked their IPRs to keep imported products out of their market. The Member States of the EU have, as a general rule, a wide discretion to govern their systems of property ownership as recognized in Article 345 TFEU. Their competence within this field is supported in the derogation clause in Article 36 TFEU, where it is stated that the protection of industrial and commercial property can justify restrictions on the free movement of goods if the relevant conditions are fulfilled.

When it comes to IPRs the Court of Justice has, in its case law, distinguished between the existence of IPR and its exercise, *i.e.* EU law does not affect the existence of an IPR which has been recognized by a Member State, but it affects the way how the IPR holder exercises its rights. Consequently, manufacturers of products have to accept that when their goods have been put on the market in the EU they are subject to exhaustion of rights, which makes it impossible to rely on IPRs to impede parallel trade.<sup>32</sup> This reflects the view that the core of an intellectual property right, such as patent, is the right to be the first to manufacture and place the product on the market. At the time when rights holder or his licensee has done so, he has exhausted all further rights over the product under the intellectual property right and can therefore not block the export of the product to other parts of the EU under parallel rights. The use of IPRs can thereby, not be used to partition national markets and to restrict the free movement of goods between Member States.<sup>33</sup> It is, however, possible for the manufacturer to rely upon its trademark to prevent repackaging and re-labeling of parallel traded goods, but according to the case law from the Court of Justice such opportunities are limited. The legal basis for exhaustion of trade marks in the EU is now stipulated in Article 7 of the trade mark harmonization Directive 89/104/EC.<sup>34</sup>

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<sup>32</sup> See Case C- 78/70 *Deutsche Grammophon v Metro*, [1971] ECR 487.

<sup>33</sup> See e.g. Cases C-16/03 *Peak Holding AB v Axolin-Elinor AB*, [2005] ECR I-11313 and C-348/04 3391 *Bohringen Ingelheim v Swingward*, [2007] ECR I-3391. See also Tumbridge, James, *Syfait II: Restrictions on Parallel Trade within the EU*, *European Intellectual Property Review*, 2008 (31) page 103 and Cook, Trevor, cited *supra* note 31, pages 394-395.

<sup>34</sup> First Council Directive (EEC) 89/104 of 21 December 1988 to approximate the laws of Member States relating to trade marks [1989] OJ L 40.

### 3.2.3 Business Practices to Limit Parallel Trade

The EU Competition rules have an important role in protecting the internal market by ensuring that competition in the internal market is not distorted. Before the Treaty on the functioning of the EU entered into force, this role was ensured in Article 3(1)(g) of the EC Treaty but it has now been recognized in Protocol 27 TFEU.

Business practices can be used to distort the internal market and hamper parallel trade and that has proved to be reality within the field of parallel trade in the pharmaceutical sector.

Actions that the pharmaceutical industry has taken aiming at limiting parallel trade have provoked considerations on the applicability of Article 101 TFEU on anti-competitive cartels and Article 102 TFEU on the abuse of a dominant position. The attempts to use business practices to limit parallel trade have mainly involved refusal to supply parallel traders, and the establishment of dual pricing systems, whereby wholesalers – exporting pharmaceutical products from low price Member States to high price Member States – have to buy the product at a higher price than other wholesalers, which do not engage in parallel trade.

As to Article 101 TFEU and anti-competitive agreements, the Court of Justice has considered agreement on export bans on pharmaceuticals, to prevent parallel trade, to infringe Article 101 TFEU.<sup>35</sup> Similarly, the Court of Justice has not been in favor of agreements on establishing dual price systems, aiming at limiting parallel trade, and has considered such conduct also to be in breach of Article 101 TFEU.<sup>36</sup> Furthermore, the Court of Justice has assessed actions taken by dominant pharmaceutical undertakings to prevent parallel trade in pharmaceuticals under Article 102 TFEU. When a pharmaceutical company in a dominant position unilaterally refuses to supply its wholesalers, such activity can be considered to be an abuse of a dominant position

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<sup>35</sup> Case C-277/87 *Sandoz Prodotti Farmaceutici v Commission*, [1990] ECR I-45.

<sup>36</sup> See e.g. Joined Cases C-501/06, 513/06, 515/06 and 519/06 *GlaxoSmithKline Services v. Commission* [2009].

under

Article

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TFEU.<sup>37</sup>

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<sup>37</sup> See *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE*, cited *supra* note 3. On the use of business practices to limit parallel importation of pharmaceuticals, in general, see Cook, Trevor, cited *supra* note 31, pages 410-414.

# 4 Competition Law and the Internal Market

As touched upon in the previous chapter, EU Competition rules play an important role in protecting the internal market by ensuring that competition in the internal market is not distorted, as now stipulated in Protocol 27 TFEU.

The role for EU competition rules in protecting the internal market has also intrigued the Court of Justice which has in this context recognized competition law as fundamental principle of law.<sup>38</sup>

## 4.1 Abuse of a Dominant Position

According to Article 102 TFEU “*any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States*”. According to this provision two conditions must be met, first the company at issue must be in a dominant position and second, the conduct must be abusive according to the provision.

When it comes to the evaluation of whether an undertaking is in a dominant position one must first and foremost look at the relevant product market and the relevant geographical market. Every case must be evaluated on its own merits but in general, undertakings with market share under 40% would not be considered to be in a dominant position.<sup>39</sup> It is also important to look at other factors than solely the market share, when assessing whether an undertaking has a dominant position. In this sense high entry

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<sup>38</sup>See Cases C-126/97 *Eco Swiss v Benetton* [1999] ECR I-3055, paras. 36-39 and C-453/99 *Courage v Crehan* [2000], ECR I-11179, paras. 20-22.

<sup>39</sup> See e.g. Communication of February 9, 2009 from the EC Commission; *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC treaty to abusive exclusionary conduct by dominant undertakings*, OJ 2009 C45/7. Available at: Available at: [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52009XC0224\(01\):EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52009XC0224(01):EN:NOT). Visited on 5 July 2010.

barriers to a market can be indicative of a dominant position. This is especially relevant within the pharmaceutical industry, which is very dependent upon patents, which in turn create high entry barriers for potential competitors.

When defining the concept abusive conduct, Article 102(2) TFEU gives some guidelines. The provision provides for a list of activities which can be considered to be abusive. It must, however, be noted that the list is non-exhaustive. According to Article 102(2) TFEU abuse may consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

A dominant undertaking's business conducts that are caught by Article 102 TFEU can either be categorized as of an exploitative character or of an exclusionary character. An abuse of exploitative character is when an undertaking uses its dominant position to obtain monopoly profits, for instance by excessive pricing or by reducing product efficiency. Exclusionary conduct, on the other hand, is conduct that aims at reinforcing the dominant undertaking's position and exclude actual or potential competitors on the market. Refusal to supply by a dominant undertaking would be categorized as an exclusionary abuse of a dominant position.<sup>40</sup>

There is a fundamental difference between the structure of the two main competition law provisions in the TFEU, namely Article 101 and 102 TFEU.

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<sup>40</sup> See e.g. Monti, G., *EC Competition Law*, Cambridge University Press, 2008, page 217.

Article 101 TFEU, prohibiting anticompetitive agreements, provides for exceptions of such prohibition in Article 101 (3) if the agreements satisfy four cumulative conditions set forth in the paragraph. First, the agreement must contribute to the improvement of the production or distribution of goods, or promote technical or economic progress. Secondly, a fair share of the benefits from the agreement must be passed on to consumers. Thirdly, the agreement may not impose restrictions on the undertakings concerned that are not indispensable to the attainment of the objectives, and fourthly it may not afford the parties the possibility of substantially eliminating competition.

First, it is necessary to consider whether an agreement falls under Article 101(1) TFEU and secondly assess if Article 101(3) TFEU is applicable. The person alleging legality has the burden of proof under Article 101(3) TFEU.<sup>41</sup>

Unlike Article 101 TFEU, Article 102 TFEU does not have an exemption clause similar to that in Article 101(3), allowing for a rule of reason based approach to abusive conduct. Therefore it might be indicated from the text of Article 102, that if the requirements of dominance and abusive conduct are met, the undertaking in question violates Article 102 TFEU *per se*.<sup>42</sup>

#### 4.1.1 Refusal to Supply as an Abuse of a Dominant Position

As a general rule the right to decide whom you want to do business with is a fundamental principle of law. Although the concept does not have a legal basis in EU law it is a fundamental contractual principle, with a strong basis in the Member States' legislation.<sup>43</sup>

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<sup>41</sup> Regulation 1/2003, OJ 2003, L1/1, Art 2.

<sup>42</sup> See e.g. Korah, Valentine, *An Introductory Guide to EC Competition Law and Practice*, Hart Publishing, 2007, page 93-94.

<sup>43</sup> Groussot, X.; Lidgard, H.H., *Are there General Principles of Community Law affecting Private Law? General Principles of EC Law in a Process of Development* (ed. Bernitz U. et al.), Kluwer Law International 2008, page 155. See also Advocate General Jacobs' opinion in C-7/97 *Oscar Bronner v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH*, [1999] ECR I-7817 where he states that; "it is apparent that the right to choose one's trading partners and freely to dispose of one's property are generally recognised principles in the laws of the Member States, in some cases with constitutional status. Incursions on those rights require careful justification." para 56.

The concept “refusal to supply” has been held to cover a broad range of practices, such as refusal to supply products to existing or new customers, refusal to license intellectual property rights or refusal to grant access to an essential facility or a network.

Article 102 TFEU does not state anything about the legitimacy of a dominant undertaking’s refusal to deal. Case law gives more guidelines on the legitimacy of the conduct. The first case on refusal to supply before the Court of Justice dates back to 1974 in *Commercial Solvents*.<sup>44</sup> *Commercial Solvents* had a dominant position on the upstream market for producing raw material that was important for producing ethambutol, a drug against tuberculosis. *Commercial Solvents* had sought to integrate on the downstream market for the producing of ethambutol, and refused to supply the raw material to Zoja, one of three makers of ethambutol in the EU. In this case the Court of Justice makes the following statement:

*“...an undertaking which has a dominant position in the market of a raw material and which with the object of reserving such raw material for manufacturing its own derivatives, refuses to supply a customer, which is itself a manufacturer of these derivatives, and therefore risks eliminating all competition on the part of this customer, is abusing its dominant position within the meaning of article 86 [Article 102 TFEU]...”*<sup>45</sup>

The refusal to supply was therefore seen as illegal *per se* under Article 102 TFEU.

It appears from the case that the Court of Justice is, at least partially, placing an emphasis on protecting competition, *i.e.* small competitors that would have difficulties in integrating into the upstream market where entry barriers were high.<sup>46</sup>

The Court of Justice did not apply as strict approach to refusal to supply in a later case, *United Brands*.<sup>47</sup> In this case *United Brands* reduced its supplies of Chiquita bananas to Olsen, one of its distributors in Denmark. Olsen was also an exclusive distributor in Denmark for the brand *Dole* and *United Brands* had argued that the reason for the

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<sup>44</sup> Joined Cases C-6/73 and 7/73 *Instituto Chemioterapico Italiano and Commercial Solvents v Commission*, [1974] ECR 223.

<sup>45</sup> *Ibid*, para 25.

<sup>46</sup> *Ibid*, para 34.

<sup>47</sup> Case C-27/76 *United Brands v Commission* [1978] ECR 207.

reduction in supply was that Olsen was selling fewer Chiquita bananas. In this case the Court of Justice makes the following statement:

*“...it is advisable to assert positively from the outset that an undertaking in a dominant position for the purpose of marketing a product – which cashes in on the reputation of a brand name known and valued by consumers - cannot stop supplying a long standing customer who abides by regular commercial practice, if the orders placed by this customer are in no way out of the ordinary...”<sup>48</sup>*

The Court then continued by recognizing a some sort of rule of reason based approach to refusal to supply, by claiming that a dominant undertaking can only take reasonable steps to ensure that its produce is sold properly. Such conduct would, however, not be accepted if the actual purpose was to strengthen the dominant position and abuse it.<sup>49</sup>

When comparing the two cases, *United Brands* and *Commercial Solvents* it must be noted that the refusal to supply in *Commercial Solvent* is likely to have had much more impact than the reduction in supplies in *United Brands*, since entry barriers to the upstream market were high.<sup>50</sup>

As stated before, the abusive nature of refusal to supply must be linked to a dominant undertaking that refuses to supply. In *Bayer*<sup>51</sup> the General Court and the Court of Justice quashed a Commission’s decision fining Bayer for infringing Article 101 TFEU by concluding agreements with its wholesalers in Spain and France to prohibit exports of the medicinal product Adalat to other Member states. The reason for this was that the EU Courts thought that the Commission had not proved that an agreement existed and therefore the activity was unilateral. In this case Bayer had failed to meet large orders when such wholesalers became major sources for parallel trade. If this conduct of Bayer was to have been considered an infringement of Article 102 TFEU one would also have to prove the existence of dominance.<sup>52</sup>

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<sup>48</sup> *Ibid*, para 182.

<sup>49</sup> *Ibid*, para 189.

<sup>50</sup> See Korah, Valentine, cited *supra* note 42, page 174.

<sup>51</sup> See Joined Cases C-2/01-C-3/01 *Bundesverband der Arzneimittel-Importeure v. Bayer*, [2004] ECR I-23.

<sup>52</sup> See e.g. Cook, Trevor, cited *supra* note 31, page 411.

In the above mentioned cases, refusal to supply goods, were concerned with the refusal to supply existing customers. The Court of Justice has though not only dealt with such cases, but also with cases concerning a first time refusal to supply, as it did in *Bronner*, which concerned refusal to supply services.<sup>53</sup> In this case Bronner was denied access to the newspapers delivery scheme in Austria, which was run by Mediaprint. In the case, AG Jacobs makes three interesting statements in his opinion in the case on refusal to supply in general. First, he recognizes the fundamental status of the right to choose one's trading partners. Second, he points out that interference with a dominant undertaking's freedom to contract is likely to reduce its incentives for investment, and such would perhaps increase short term competition but reduce it in the long term. Third, he emphasized that the primary purpose of Article 102 TFEU was to safeguard the interests of consumers rather than to protect the position of particular competitors.<sup>54</sup>

In this case the Court of Justice held that if Mediaprint was considered to be in a dominant position on the market there could be an abuse of dominant position if (i) the refusal was likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service; (ii) the refusal was incapable of being objectively justified; and (iii) the service in itself was indispensable to carrying on that person's business, inasmuch as there is no actual or potential substitute in existence for the home delivery scheme.<sup>55</sup> In this case the court came to the conclusion that these conditions were not met since other methods of distributing news papers existed.<sup>56</sup>

Closely related to the question of refusal to supply products is the legal question of when an undertaking in a dominant position is obliged to grant a license to other undertakings. Intellectual property rights often confer dominant position on the holder, and an obligation to license would be likely to reduce the value of the intellectual property right.<sup>57</sup>

In *Volvo*<sup>58</sup> the Court of Justice held that the rights to restrain third parties from exploiting design right constituted the very subject-matter of his exclusive right. If the IPR holder

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<sup>53</sup> See case C-7/97 *Oscar Bronner v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH*, cited *supra* note 43.

<sup>54</sup> *Ibid*, paras. 56-58.

<sup>55</sup> *Ibid*, para 41.

<sup>56</sup> *Ibid*, para 43.

<sup>57</sup> Korah, Valentine, cited *supra* note 42, pages 175-176.

<sup>58</sup> Case C-238/87, *Volvo AB v Erik Veng*, [1988] ECR 6211.

would be ordered to grant a license it would deprive it of the substance of its exclusive right and the refusal to license would therefore not constitute an abuse of a dominant position. However, the Court took precautions against such activities by stating that the exercise of the IPR holder's right might be abusive under Article 102 TFEU if it involved:

*"...certain abusive conduct such as the arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation, provided that such conduct is liable to affect trade between Member States."*<sup>59</sup>

The Court of Justice did not decide whether Volvo had a dominant position on the market but according to this case it seems, like the proprietor of an exclusive right may be obliged to license or supply third parties on terms that are not considered 'unfair'.<sup>60</sup>

The Court of Justice ruled on the question of refusal to license again in *Magill*<sup>61</sup>. In this case Magill sought to publish a guide containing programs for the TV channels in Ireland, but was prevented to do so since it infringed the TV channels' copyright. The Court of Justice came to the conclusion that this conduct was to be considered an abuse of a dominant position because of the special circumstances of the case. It made the following statement:

*"The appellants' refusal to provide basic information by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential demand. Such refusal constitutes an abuse under heading (b) of the second paragraph of Article 82 of the Treaty [Article 102 TFEU]."*<sup>62</sup> The Court then continued by stating that the refusal was not justified.<sup>63</sup>

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<sup>59</sup> *Ibid*, para 16.

<sup>60</sup> Korah, Valentine, cited *supra* note 42, page 176.

<sup>61</sup> Joined Cases C-241/91-242/91, *Magill TV Guide*, [1995] ECR-I 743.

<sup>62</sup> *Ibid*, para 54.

<sup>63</sup> *Ibid*, para 56.

## 4.1.2 Refusal to Deal in the EU and the USA

When it comes to comparing the approach to a dominant company's refusal to deal in the EU and the USA, it has been held that the EU approach is more formalistic than the approach in the USA to such conduct. In this context it has also been stated that the EU places more emphasis on protecting competitors than safeguarding the dominant undertaking's leeway to choose its methods of making business.<sup>64</sup> The EU approach has also been held to be problematic as it supposedly neglects the possible economic efficiency gain in the long term and instead focuses on short term interests of consumers. This has even been considered to reduce the incentives for dominant undertaking's investment in certain areas, since access might be granted to their competitors on ground of Article 102 TFEU.<sup>65</sup>

## 4.1.3 The 2009 Guidance

On 9 February 2009 the Commission published Guidelines on its enforcement priorities in applying Article 102 TFEU to abusive exclusionary conduct by dominant undertakings. The guidelines do not cover dominant undertaking's exploitative conduct.<sup>66</sup> The guidelines focus is on four kinds of abuses; exclusive dealing, tying and bundling, predation, and finally refusal to supply and margin squeeze<sup>67</sup>.

When it comes to refusal to supply the Commission accepts that undertakings should, as a general rule, have the right to choose their trading partners and dispose freely of their property. If not, unnecessary intervention could hamper incentives for investment and innovation and harm consumers in the long run.<sup>68</sup>

In the guidelines it is stated that the Commission will consider refusal to supply as an enforcement priority if three conditions are met. First, the refusal must relate to a

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<sup>64</sup> Forrester, Ian S., *Article 82: Remedies in Search of Theories?*, 28 Fordham Int'l L.J., 2004, page 920.

<sup>65</sup> Nagy, Csongor Istvan *Refusal to Deal and The Doctrine of Essential Facilities in US and EC Competition Law: A Comparative Perspective and Proposal for a Workable Analytical Framework*, European Law Review, Vol. 32, No.5, 2007, pages 664-685.

<sup>66</sup> Cited *supra* note 39.

<sup>67</sup> *Ibid*, para 7.

<sup>68</sup> *Ibid*, para 75.

product or service that is objectively necessary to be able to compete effectively on a downstream market. Second, the refusal must be likely to lead to the elimination of effective competition on the downstream market and third, the refusal is likely to lead to consumer harm.<sup>69</sup>

If the above mentioned three conditions are met, the Commission will consider claims by the dominant undertaking that a refusal is necessary to allow the dominant undertaking to realize an adequate return on the investment required to develop its input business, thus generating incentives to continue to invest in the future. The Commission will also consider claims by the dominant undertaking that its own innovation will be negatively affected by the obligation to supply. In this, the Commission must balance the interests at stake, *i.e.* the anti competitive effects and the possible efficiency gains.<sup>70</sup> This proposed approach brings the application of Article 102 TFEU closer to the application of Article 101(3) TFEU where the anti-competitive effects and pro-competitive benefits of an agreement are balanced.<sup>71</sup>

## 4.2 Abusive Conduct Restricting Parallel Trade

The cases analyzed above, concerned mainly the refusal to deal not aiming at limiting parallel trade. As we saw in chapter three, concerning restrictions to parallel trade in pharmaceuticals, the Court of Justice has not favored such restrictions since they strike at the very heart of the internal market.

Chapter three was only concerned with restrictions to parallel trade within the pharmaceutical sector, but if we look at cases concerning abusive conduct restricting parallel trade within other sectors we can see that the Court of Justice has approached such conduct in a restrictive manner.

The activity of parallel trade has been especially tempting within fields where there are noticeable differences in prices between products in different Member States. In respect of sectors other than the pharmaceutical sector, the Court of Justice has held that a

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<sup>69</sup> *Ibid* para 81.

<sup>70</sup> *Ibid* paras. 89-90.

<sup>71</sup> See Commission Guidelines on the Application of Article 81(3) of the Treaty, [2004] OJ C101/97, para 11.

practice by which an undertaking in a dominant position aims to restrict parallel trade in the products that it puts on the market constitutes abuse of that dominant position, particularly when such a practice has the effect of curbing parallel imports by neutralising the more favourable level of prices which may apply in other sales areas in the EU or when it aims to create barriers to re-importations which come into competition with the distribution network of that undertaking.<sup>72</sup> Consequently the Court's opinion has been that parallel imports enjoy a certain amount of protection in EU law because they encourage trade and help reinforce competition.<sup>73</sup>

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<sup>72</sup> See case C-26/75 *General Motors Continental v Commission*, [1975] ECR 1367, para 12 and C- 226/84 *British Leyland v Commission*, [1986] ECR 3263, para 24.

<sup>73</sup> See case C-373/90 X, [1992] ECR I-131, para 12.

# 5 Refusal to Supply and the Pharmaceutical Industry

As has been mentioned before, refusal to supply is one of the business conducts that pharmaceutical undertakings have applied to restrict parallel trade within the pharmaceutical sector.

The question of whether such conduct, when applied by a dominant undertaking, can be considered to be an abuse of a dominant position was first raised in *Syfait I*.<sup>74</sup> On procedural grounds, The Court of Justice did not rule on the matter and stakeholders were left with the essential question unanswered. However, the opinion of Advocate General (AG) Jacobs, in the case is worthy of note and deserves an in depth coverage.

Shortly after the Court of Justice dismissed *Syfait I*, another case was brought before the Court of justice to attain legal clarity in *Sot. Lelos kai sia*.<sup>75</sup>

The following chapters endeavor to analyze how the legal question is dealt with by the Court of Justice. Since AG Jacobs and Colomer raised some important points in their opinions, worthy of note, there will also be a separate discussion of those opinions.

## 5.1 C-53/03 Syfait v GlaxoSmithKline

In this case the Greek Competition Commission asked the Court of Justice to give a preliminary ruling on the question of whether it was in conformity with Article 102 TFEU for a dominant firm to refuse to supply pharmaceuticals to wholesalers in order to limit parallel trade.

The facts of this case are that Greek wholesalers had complained that GlaxoSmithKline (GSK) had ceased to meet their orders in full for three medicines. In the case GSK had

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<sup>74</sup> Case C-53/03 *Syfait v GlaxoSmithKline* [2005] ECR I-4609.

<sup>75</sup> See *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE*, cited *supra* note 3.

stated that it would only supply hospitals and pharmacies directly and held that parallel exports by the wholesalers had created significant shortages on the Greek market. The Court of Justice came to the conclusion that the Greek Competition Commission was not a court or a tribunal within the meaning of Article 267 TFEU and did therefore not rule on the matter.<sup>76</sup> As a consequence, stake holders were left with this important question unanswered.

### 5.1.1 Advocate General Jacobs in *Syfait v GlaxoSmithKline*

Unlike the Court of Justice, AG Jacobs did not dismiss the case on procedural grounds and made an effort to analyze the specific characteristics of the pharmaceutical industry and the difficulties it undergoes on the open internal market of Europe.

AG Jacobs comes to the conclusion that a dominant pharmaceutical company, restricting supply to wholesalers, does not necessarily abuse its dominant position under Article 102 TFEU, although the purpose of the conduct is to limit parallel trade. According to him, such conduct may plausibly be one of the circumstances, which will make refusal to supply abusive, but such conduct is, however, capable of objective justification.<sup>77</sup> He lists three reasons to support that argument.

First, a dominant undertaking will only occasionally have an obligation to supply its products or services. That could, for instance, be the case where an interruption of supply would seriously disrupt competition between the undertaking and the customer on a downstream market or between the undertaking and its actual or potential competitors on the market of supply.<sup>78</sup>

Second, he points out that a dominant undertaking's obligation to supply under Article 102 TFEU is in various respects circumscribed. As an example of this he refers to *United Brand* where a dominant undertaking was not obliged to meet orders which were

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<sup>76</sup> See *Syfait v GlaxoSmithKline*, cited *supra* note 74, paras 35-37

<sup>77</sup> Opinion of AG Jacobs in *Syfait v GlaxoSmithKline*, paras. 69-71,

<sup>78</sup> *Ibid*, para 66.

out of the ordinary and consequently it was entitled to take steps that were reasonable to defend its commercial interests. He also states that the Court has consistently limited the obligation upon dominant undertakings by reference to the possibility of objective justification.<sup>79</sup>

Third, he points out that the factors, which go to demonstrate whether an undertaking's conduct in refusing to supply is abusive or not, are highly dependent on the specific economic and regulatory contest in which each case arises.<sup>80</sup>

When estimating whether the refusal to supply can be objectively justified, AG Jacobs states that three factors must be taken into account; first, the pervasive regulation of price and distribution in the sector; second, the likely impact of unmoderated parallel trade upon pharmaceutical undertakings in the light of the economics of the sector; and third, the effect of such trade upon consumers and purchasers of pharmaceutical products.

First, he focuses on the regulation of price and distribution in the European pharmaceutical sector and states that it is impossible to ignore the pervasive and diverse regulation which the pharmaceutical sector is subject to, both at national level and EU level, which distinguishes it from other industries engaged in the production of readily traded goods. Since Member States intervene to limit the prices payable for medicinal products within their territory, the price of pharmaceuticals vary greatly between Member States, which makes the sector attractive for parallel trade. Furthermore, many Member States place duties on pharmaceutical manufacturers and wholesalers to guarantee the availability of medicinal products, and so does Article 81 of Directive 2001/83. AG Jacobs believes that the legal and moral obligations for pharmaceutical manufacturers to ensure supplies makes it doubtful, whether it is reasonable and proportionate to require such manufacturers to supply wholesalers in low-price Member States engaging in parallel trade.<sup>81</sup>

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<sup>79</sup> *Ibid*, para 67.

<sup>80</sup> *Ibid*, para 68.

<sup>81</sup> *Ibid*, paras. 77-88.

Second, AG Jacobs considers some of the economic factors affecting the commercial policy of pharmaceutical undertakings. He recognizes that innovation is an important parameter of competition in the pharmaceutical sector and that the production of pharmaceutical products is characterized by high fixed costs relating to R&D, and relatively low variable costs relating to the manufacturing of a product. The decision whether to invest in the development of a new pharmaceutical product will obviously depend in part upon whether the producer expects to be able to make sufficient profits to recoup the cost of investment. Once the investment is made, however, that cost is sunk and it is therefore rational for an undertaking to supply its products on any market where price is fixed above variable cost. He notes that these factors create a risk of pharmaceutical undertakings delaying the launch of new products in lower priced Member States to avoid supplying parallel traders. This would, in turn, lead to more fragmented markets with a differing range of products available from one Member State to another.<sup>82</sup>

Third, AG Jacobs casts doubts on the postulation that parallel trade in pharmaceuticals will benefit consumers in reduced prices. His arguments for this is that in many Member States patients make only a small flat rate contribution towards the price of pharmaceutical products which are prescribed to them, and the rest is paid by the social health insurance system. He also states that parallel trade does not always result in price competition to the benefit of the public bodies, which in fact purchase the traded products, or taxpayers, since the price differential resulting from parallel trade is often absorbed by those involved in the distribution chain.<sup>83</sup>

## **5.2 Joined Cases C-468/06-C-478/06 Sot. Lelos kai Sia EE v GlaxoSmithKline AEVE**

In 2008, three years after the Court of Justice dismissed the *Syfait I* case, another case with the same legal matter was brought before the Court of Justice by the Appeal Court

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<sup>82</sup> *Ibid*, paras. 89-95.

<sup>83</sup> *Ibid*, paras. 96-99.

in Athens in *Sot. Lelos kai Sia*.<sup>84</sup> The Appeal Court directly asked the Court of Justice whether a pharmaceutical undertaking's refusal to meet the orders of wholesalers to limit parallel trade is to be seen as a *per se* abuse within the meaning of Article 102 TFEU. Furthermore, if limitation of parallel trade does not constitute an abusive practice in every case, how is possible abuse to be assessed?

### 5.2.1 Advocate General Colomer in *Sot. Lelos kai Sia*

Unlike AG Jacobs, AG Colomer relied on prior case law from the Court of Justice and stated that a dominant undertaking which avoids supplying goods, particularly when there are no substitutes, and reserves to itself the parallel export market, commits an abuse under Article 102 TFEU.<sup>85</sup> However, he provided a framework for consideration of the question of whether the conduct could be objectively justified. According to him such a conduct could possibly be justified if the dominant undertaking could prove one of the following; first, that matters relating to market regulation constrain it to refuse to supply wholesalers; second, that its sole motivation was the protection of its legitimate business interests which do not include, in this case, the impact on incentives to innovate; or third, the economic benefits of its conduct. When the grounds for justifications have been established, AG Colomer pointed out that the proportionality test should not be overlooked.<sup>86</sup>

AG Colomer was of the opinion that the pharmaceutical company in this case could not prove that any of the possible justifications was applicable.

AG Colomer agreed with GSK that the EU market for pharmaceuticals did not operate under normal competitive conditions because of Member states' influence on the pricing of medicinal products. However, he was of the opinion that manufacturers of medicinal products could have some influence in negotiating prices with Member States health authorities, and therefore they enjoy a degree of strength in the market.<sup>87</sup> Furthermore

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<sup>84</sup> See *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE*, cited *supra* note 3.

<sup>85</sup> Opinion of AG Colomer in *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE*, para 46.

<sup>86</sup> *Ibid.* paras. 121-122.

<sup>87</sup> *Ibid.* para 93.

AG Colomer rejected GSK's argument that its duty to keep the Greek market adequately supplied at all times prevents it from meeting all orders from wholesalers.<sup>88</sup>

### 5.2.2 The Court of Justice in *Sot. Lelos kai Sia*

In its judgment, the Court of Justice first states that according to settled case law the existence of refusal to supply by a dominant undertaking is liable to eliminate competition.<sup>89</sup> Subsequently the Court analyses whether the conduct is to be considered abusive.

First, the Court of Justice assesses GSK's argument that parallel trade in any event brings only few financial benefits to the ultimate consumers. According to the Court of Justice it is not necessary for the Court to base its assessment on whether parallel trade will benefit the final consumer of medicinal products. However, the Court states that the final consumer in the importing Member State will not necessarily benefit as much as the wholesalers carrying out the parallel exports. Nevertheless, the Court is of the opinion that although prices of medicines are subject to State regulation, parallel trade is liable to exert pressure on prices and, consequently, to create financial benefits not only for the social health insurance funds, but equally for the patients concerned.<sup>90</sup>

Next the Court of Justice estimates the impact of State price and supply regulation in the pharmaceutical sector. In line with AG Colomer the Court of Justice states that the control exercised by Member States over the selling prices or the reimbursement of medicinal products does not entirely remove the prices of those products from the law of supply and demand. Furthermore, the Court notes that where a medicine is protected by a patent which confers a temporary monopoly on its holder, the price competition which may exist between a producer and its distributors, or between parallel traders and national distributors, is, until the expiry of that patent, the only form of competition which can be envisaged. Thus, the Court comes to the conclusion that there can be no escape from the prohibition laid down in Article 82 EC for the practices of an undertaking in a

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<sup>88</sup> *Ibid.* paras. 94-97.

<sup>89</sup> See *Sot. Lelos kai Sia EE v. GlaxoSmithKline AVEE*, cited *supra* note 3, para 34.

<sup>90</sup> *Ibid.*, paras. 53-57.

dominant position which are aimed at avoiding all parallel exports from a Member State to other Member States, since those practices partition the national markets and neutralize the benefits of effective competition in terms of the supply and the prices that those exports would obtain for final consumers.

As to the argument of GSK that parallel trade might affect the marketing of new products in low price Member States, the Court clearly states that EU competition rules are incapable of being interpreted in such a way that, in order to defend its own commercial interest, the only choice left for a pharmaceutical undertaking is not to place its medicines on the market at all in a Member State where prices of the product are relatively low.<sup>91</sup>

The crucial issue, when assessing whether the actions of a pharmaceutical company are reasonable and proportional in order to protect its legitimate interests is to assess whether they are out of the ordinary. According to the Court it is permissible for a pharmaceutical company to counter in a reasonable and proportionate way the threat to its own commercial interests potentially posed by the activities of an undertaking which wishes to engage in parallel trade.<sup>92</sup>

As expected, the Court of Justice did not carry out the proportionality test itself but left it to the national court to make the assessment of whether the orders in the case were ordinary in the light of both the previous business relations between the pharmaceutical company holding a dominant position and the wholesalers concerned, and the size of the orders in relation to the requirements of the market in the Member State concerned.<sup>93</sup>

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<sup>91</sup> *Ibid*, para 68.

<sup>92</sup> *Ibid*. paras. 70-71.

<sup>93</sup> *Ibid*, para 73.

### 5.3 The Aftermath of *Sot. Lelos kai Sia*

Shortly after *Sot. Lelos kai Sia*, the Court of Justice gave its ruling in the case *GSK v Commission*<sup>94</sup>, a case concerning dual pricing of pharmaceuticals aimed at restricting parallel trade.

Before the Court of Justice gave its ruling in *GSK v Commission* the General Court ruled on the matter<sup>95</sup> and came to the conclusion that the application of Article 101(1) TFEU cannot depend solely on the fact that the agreement on dual pricing is intended to limit parallel trade or to partition the market, since it also requires an analysis. Such analysis should be designed to determine whether the agreement has as its object or effect the prevention, restriction or distortion of competition on the relevant market, to the detriment of the final consumer.<sup>96</sup>

The Court of Justice, however, came to a similar conclusion as it did in *Sot. Lelos kai Sia*, confirming that an agreement aiming at limiting parallel trade shall be considered as restrictive of competition by its object. It therefore held that the General Court committed an error of law, when it came to the conclusion that such agreements could only be considered to be anti-competitive by object, if their object or effect was shown to be a restriction of competition to the detriment of the final consumers.<sup>97</sup>

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<sup>94</sup> See *GlaxoSmithKline Services v. Commission*, cited *supra* note 36.

<sup>95</sup> Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II-2969.

<sup>96</sup> *Ibid*, para. 119.

<sup>97</sup> See *GlaxoSmithKline Services v. Commission*, cited *supra* note 36, paras. 63-64.

## 6 The Economic Effects of Refusal to Supply Pharmaceuticals to Parallel Traders

In *Sot. Lelos kai Sia* the Court of Justice has indicated that a dominant undertaking's possibility for refusing to supply wholesalers will only apply under exceptional circumstances. The Court of Justice was not as willing to grant the pharmaceutical sector some sort of immunity like AG Jacobs suggested in his opinion.

Unlike AG Jacobs, the Court of Justice chose to protect full market integration and emphasized that there could be no escape from the prohibition laid down in Article 102 TFEU for the practices of an undertaking in a dominant position aiming at avoiding all parallel exports. Such practices would partition the national markets, and neutralize the benefits of effective competition in terms of the supply and the prices that those exports would obtain for final consumers in the other Member States.<sup>98</sup> At present the Court of Justice has indicated that a dominant undertaking's possibility for refusing to supply wholesalers will only apply under exceptional circumstances.

As to the argument from GSK that the profit of parallel trade would go to the wholesalers, not consumers, the Court held that such trade would however be liable to exert pressure on prices that would eventually benefit consumers.<sup>99</sup> Regarding different price regulation in Member States, the Court held that although such regulation existed, the pharmaceutical undertakings would still have some say in the price setting process. The existence of price control and reimbursement of medicinal cost did therefore not entirely remove the prices of those products from the law of supply and demand.<sup>100</sup> Furthermore, the Court did not accept GSK's argument that the only choice left for pharmaceutical companies would be not to place their products on the market in low

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<sup>98</sup> See *Sot. Lelos kai Sia EE v. GlaxoSmithKline AVEE*, cited *supra* note 3, para 66.

<sup>99</sup> *Ibid*, paras. 54-57.

<sup>100</sup> *Ibid*, paras. 61-63.

price Member States, since it would go against the objective of competition law to protect consumers by means of undistorted competition and market integration.<sup>101</sup>

However, the Court recognized that a pharmaceutical company could take reasonable and proportionate steps to protect its own commercial interests. To fulfill the conditions of being reasonable and proportionate, it must be ascertained whether the orders from the wholesalers are out of the ordinary, before a pharmaceutical in a dominant position can refuse to supply.<sup>102</sup>

The question of the economic effects of the Court's approach is a complex and controversial one and there are divergent views on who actually benefits from parallel trade in pharmaceuticals.

When analyzing the economic effects of the Court's approach to refusal to supply parallel traders it is appropriate to use AG Jacobs' approach as a starting point and divide the discussion into two questions. First, whether parallel trade will eventually benefit consumers with lower prices of medicinal products. Second, whether parallel trade is likely to harm consumers with reduced expenditure on R&D and with delay in the launch of new medicinal products.

## **6.1 The Impact of Parallel Trade in Pharmaceuticals on Prices in the EEA States**

Parallel trade forms an integral part of the principle of free movement of goods, which aim is to efficiently allocate resources within the EEA to the benefit of consumers. Consequently, the economic rationale for facilitating parallel trade is that it will lead to reduced prices for consumers. But is that reality when it comes to parallel trade in pharmaceutical products? Will the arbitrage of such trade directly lead to lower prices for consumers or will the profit vanish long before the consumer takes up his wallet, and end up with the wholesaler engaged in such trade?

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<sup>101</sup> *Ibid*, para 68.

<sup>102</sup> *Ibid*, para 69-70.

Economic theory predicts that the exercise of parallel trade will have the effect that prices will go up in the exporting countries while prices in the importing countries decline. If the markets are not regulated and there is no product differentiation, parallel trade will lead to a “race to the bottom” in the importing country, where price equals marginal cost.<sup>103</sup>

Since the domestic markets for pharmaceutical products are often highly regulated economic theory might be of little relevance in the context of parallel trade in pharmaceuticals. In recent years some economic researches have been conducted on the matter and the results are not unanimous.

In a research carried out by the *University of Southern Denmark* in 2006 on the economic impact of parallel trade in pharmaceuticals<sup>104</sup>, the results were that parallel trade in pharmaceuticals generates considerable direct savings to consumers as well as the health care financing systems.<sup>105</sup>

Similar conclusions had also been introduced in a research conducted by *York Health Economics Consortium* in 2003<sup>106</sup> where the main conclusion was that parallel trade in pharmaceuticals results in direct and indirect savings for the health care financing systems, pharmacists, and patients.<sup>107</sup>

However, in a research on the economic impact of pharmaceutical parallel trade conducted by *LSE Health and Social Care* in 2004<sup>108</sup>, the results were different. According to the research, patients do not benefit directly from parallel trade and the benefits accruing to health insurance organizations are, at the best, modest. Pharmacists could realize modest financial benefits in countries where there are financial incentives for products imported by parallel importers or where the wholesale market does not operate under fixed margins.

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<sup>103</sup> Tirole J. *The theory of Industrial Organisation*, Cambridge Massachusetts: MIT Press, 1989.

<sup>104</sup> Enemark, Ulrika; Pedersen, Kjeld Møller; Sørensen, Jan, *The economic impact of parallel import of pharmaceuticals*, University of Southern Denmark, 2006.

<sup>105</sup> *Ibid*, The main conclusions of the research are summarised on pages 66-69.

<sup>106</sup> West, Peter; Mahon, James, *Benefits to Payers and Patients from Parallel Trade*, York Health Economics Consortium, 2003.

<sup>107</sup> *Ibid*. The main conclusions of the research are summarized on pages 67-69

<sup>108</sup> See Kanavos, Costa-i-Font, *et.al.*, cited *supra* note 9

As could be predicted, parallel importers realize significant benefits in comparison with other stakeholders, while manufacturers incur a significant loss of business in importing countries. The conclusion of the research is that this reduces manufacturers' overall profitability, without necessarily increasing societal welfare.<sup>109</sup>

## 6.2 The Impact of Parallel Trade in Pharmaceuticals on R&D

### 6.2.1 Reduced Expenditure on R&D

Although consumers in importing countries might benefit to some extent from parallel trade in pharmaceuticals, such benefits might be offset since the loss that pharmaceutical undertakings have to face might result in less investment in innovation in the long term. AG Jacobs placed an emphasis on this issue in his opinion.<sup>110</sup>

The opinion of AG Jacobs in *Syfait I* has been criticized by scholars for not taking into account the importance of market integration, as well as it has been stated that there is no evidence suggesting that parallel trade in pharmaceuticals will impede R&D.<sup>111</sup> At the same time evidence shows that parallel trade leads to decrease in profit for pharmaceutical companies, and such loss in profit can hold back innovation within the pharmaceutical industry.<sup>112</sup>

It might be difficult to show that the decrease in profit, suffered by pharmaceutical companies due to parallel trade, has direct effect on cost incurred in R&D. However, it cannot be neglected that the pharmaceutical market is characterized by a high degree of innovation and therefore it must be assumed that a large part of the industry's expenditure is spent on R&D. Loss in profit, must therefore be likely to effect in reduced expenditure on that item of expenditure.

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<sup>109</sup> *Ibid*, The main conclusions of the research are summarised on pages 135-139.

<sup>110</sup> See Opinion of AG Jacobs in *Syfait v GlaxoSmithKline*, paras. 89-95.

<sup>111</sup> See e.g. Koenig and Engelman, *Parallel Trade Restrictions in the Pharmaceuticals Sector on the test Stand of Article 82 EC – Commentary on the Opinion of Advocate General Jacobs in the Case Syfait/GlaxoSmithKline*, ECLR, 2005(6), pages 338-348 and Enemark, Ulrika et. Al. Cited supra note 104, page 66.

<sup>112</sup> See Kanavos, Costa-i-Font, *et.al.*, cited supra note 9, page 138.

In *Sot lelos kai Sia*, The Court of Justice did not consider it necessary to examine the argument, raised by GSK, that it is necessary for pharmaceutical companies to limit parallel exports in order to avoid the risk of a reduction in their investments in R&D of medicines. However, the Court indicated that pharmaceutical companies could counter in a reasonable and proportionate way the threat that such undertakings place on their commercial interests if the orders were out of the ordinary.<sup>113</sup>

In *GSK v Commission*<sup>114</sup> concerning dual pricing aimed at limiting parallel trade, the Court of Justice took an interesting stand regarding GSK's argument that actions to limit parallel trade were necessary to safeguard innovation. In its decision, the Commission had disregarded the argument, stating that it could not be presumed that savings originating from limitation of parallel trade were destined to be R&D investments.<sup>115</sup> The Court of Justice criticized the Commission for failure to examine GSK's evidence.<sup>116</sup> However, The Court of Justice did not make an attempt to formulate criteria according to which it can be said that increased profits are devoted to R&D, which leaves companies with uncertainty regarding this question.<sup>117</sup> It must also be kept in mind that this case concerned possible exemption of an anti-competitive agreement under Article 81(3) TFEU, and consequently similar assumptions may not necessarily be mirrored when it comes to assessing a dominant company's refusal to supply under Article 102 TFEU, since that provision does not include such an exemption clause. However, as noted above, according to the new guidelines from the Commission on enforcement priorities in applying Article 82 EC (now Article 102 TFEU) to abusive exclusionary conduct by dominant undertakings, the Commission will consider claims by dominant undertakings regarding negative effects of refusal to supply on innovation, and balance the anti competitive effects and the possible efficiency gains.<sup>118</sup>

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<sup>113</sup> See *Sot. Lelos kai Sia EE v. GlaxoSmithKline A EVE*, cited *supra* note 3, paras 70-71.

<sup>114</sup> See *GlaxoSmithKline Services v. Commission*, cited *supra* note 36.

<sup>115</sup> Decision 2001/791 relating to proceeding pursuant to Article 81 of the EC Treaty Cases, [2001] OJ C275/17, para.156.

<sup>116</sup> *Ibid*, para 104.

<sup>117</sup> Petrucci, Carlo, *Parallel trade of pharmaceutical products: the ECJ finally speaks-Comment on GlaxoSmithKline*, E.L.Rev. April 2010, pages 283-284.

<sup>118</sup> See *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC treaty to abusive exclusionary conduct by dominant undertakings*, cited *supra* note 39, paras. 89-90.

## 6.2.2 Delay in Launch of New Medicinal Products

Apart from arguing that parallel trade could affect innovation, GSK argued that the consequences of parallel trade could cause a delay in the launch of new products in low price Member States.<sup>119</sup> The Court of Justice, unsurprisingly, rejected this argument, since competition rules were incapable of being interpreted in such a way that this was the only choice left for pharmaceutical companies to protect their commercial interest.<sup>120</sup>

Sarcastic or not, according to recent announcement from some large pharmaceutical companies, this appears to be the last straw for some undertakings to protect their commercial interests. Following a proposed price cut in medicines in Greece, large pharmaceutical companies have decided to withdraw their medicinal products from the Greek market.<sup>121</sup>

Such actions must be considered as having serious harmful effects for patients in low price Member States. This applies especially when no generic drugs exist for the medicinal products at issue. It still remains unclear how many pharmaceutical companies are considering withdrawing their products from low price Member States, and therefore it is difficult to estimate the eventual consequences of such conduct for consumers. Such conduct, by dominant companies, could however be considered to be abusive under Article 102 TFEU.<sup>122</sup>

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<sup>119</sup> See *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE*, cited *supra* note 3, para. 44

<sup>120</sup> *Ibid*, para. 68.

<sup>121</sup> See e.g. Novo pulls drugs from Greece over price cuts, 31 May 2010, available at: <http://www.reuters.com/article/idUSLDE64U1CV20100531>

## 7 Concluding Remarks

In chapter one it was declared that the aim of this thesis would be to investigate parallel trade in the pharmaceutical industry and particularly to explain how special the pharmaceutical industry is in the view of the Court of Justice, and furthermore which are the economic impacts of the Court's approach.

When analyzing the case law from the Court of Justice on parallel trade in pharmaceuticals, one can notice that the Court has been keen on facilitating parallel trade within the industry. This can be seen in the Court's case law concerning regulatory barriers to parallel trade, its development of the concept of exhaustion of IPRs, and through its case law on the application of EU Competition law to parallel trade. In this context, the recent ruling in *Sot. Lelos kai Sia* has achieved great attention and been a bone of contention for scholars and stake holders. The ruling gives the impression that the Court is unwilling to provide special treatment for parallel trade in pharmaceuticals on grounds of the industry's distinct characteristics. Instead, the Court of Justice has emphasized the importance of the functioning of the internal market and the free movement of goods, which is the cornerstone for parallel trade within the EU. However, although favoring the free movement of pharmaceutical products, it cannot be neglected that the Court of Justice is willing to give pharmaceutical companies some leeway to take actions to protect their commercial interests. The exact scope of this leeway is nevertheless uncertain and will most likely be defined more precisely in future case law.

The Court's approach to parallel trade in pharmaceuticals shouldn't come as a surprise when analyzed in context with one of the original goals of European integration; to create an internal market without barriers to cross-border trade, which has proved to be one of the greatest achievements of the EU. However, as has been stated above, not everyone agrees with the Court's approach, and the voices against facilitating parallel trade in pharmaceuticals have been loud. Those concerns were highlighted in the opinion of AG Jacobs in *Syfait I* and his arguments for special treatment of

pharmaceuticals were by many considered convincing. It must be accepted that the pharmaceutical industry is in many ways distinct from other industries, *inter alia* because of the necessity of great investment in innovation, its special regulatory framework, and due to the special framework for price developments in different Member States. It must, however, also be recognized that the industry does not enjoy any immunity from the general rules of the Internal Market in the EU Treaty, and therefore it is questionable whether the Court of Justice has competence to apply progressive interpretation of the TFEU to the effect of exempting this industry from some of the fundamental rules underlying the EU. Therefore all talk about disallowing parallel trade in pharmaceuticals is untimely as EU law now stands.

The question of who actually benefits from parallel trade at the end of the day is not an easy one. Probably consumers to some extent and governments in the Member States to an even more extent, since they often pay a significant part of the price for pharmaceuticals. Member States' profit from such trade is however likely to end in the pocket of consumers, who finance the health system through taxes, and therefore to benefit consumers indirectly. Undisputed, most of the profit is likely to end in the pocket of the wholesalers engaged in parallel trade in pharmaceuticals, and therefore all talk about such trade being primarily for the benefit of consumers is misleading. Contrary to this, the pharmaceutical undertakings – which have invested in the development of the pharmaceutical product at issue – do not gain from such trade, which explains their campaign against it. Reduced profits for pharmaceutical companies will probably affect the budget spent on innovation to the detriment of potential patients. Even more seriously, pharmaceutical companies can decide to withdraw their products from low price markets. This threat appears to be especially evident at the moment when low price Member States are continuing to cut prices of medicines.

Although the Court of Justice has not treated parallel trade on ground of its special characteristics hitherto, this does not mean that things cannot or should not change in the future. The Court's approach has been consequent with the legal environment as it is today. But as the Court self pointed out in *Merck & Co Inc v Primecrown Ltd*, derogation from the principle of free movement of goods is not justified, although the

imposition of price controls may distort competition between Member States. Distortions caused by different price legislation in Member States must be remedied by measures taken by the EU, not by the adoption of measures incompatible with the rules of free movement of goods.<sup>123</sup> Harmonization on EU level could nevertheless prove to be difficult for several reasons. As has been mentioned above, Member States have the competence under Article 168 TFEU to control their public health matters. In spite of this, harmonizing measures could possibly be enacted under Article 114 TFEU, the main legislative source for harmonizing the internal market. Such harmonization could however be unachievable for political reasons, since there are still great differences between public health policies in the Member States. Those differences have even become greater after the enlargement of the EU to the Eastern European countries in 2004 and 2007.<sup>124</sup> After taking these aspects into consideration it is not likely that we will see a harmonized legislation within this industry in the near future, and meanwhile, case law from the Court of Justice favoring parallel trade in pharmaceuticals remains the law.

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<sup>123</sup> See *Merck & Co Inc v Primecrown Ltd*, cited *supra* note 21, para. 47.

<sup>124</sup> See Snell, Jukka, *Free Movement of Pharmaceutical Products: An Overdose of Cheap Drugs?* EBLR, 2003(14), pages 519-520.

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