TALLINN UNIVERSITY OF TECHNOLOGY
Faculty of Social Sciences
Tallinn Law School

Enni Kranni

Parallel Trade in Pharmaceuticals – Considering the Special Nature of the Pharmaceutical Market in EU Competition Law

Master's Thesis

Supervisor: Pawan Dutt, MA, Lecturer

Tallinn 2014

I hereby declare that I am the sole author of this Master's Thesis
and it has not been presented to any other university of examination.

Enni Kranni
" ..... " 2014

The Master's Thesis meets the established requirements

Supervisor Pawan Dutt
" ..... " 2014

Accepted for examination " ..... " 2014

Board of Examiners of Law Master's Theses

……

Table of Contents

List of Abbreviations

ATC	Anatomical Therapeutic Classification
CFI	Court of First Instance
CTMR	Community Trade Mark Regulation
EAEPC	European Association of Euro-Pharmaceutical Companies
EEA	European Economic Area
EC	European Community
ECJ	European Court of Justice
EFPIA	European Federation of the Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
FCCA	Finnish Competition and Consumer Authority
FDA	Federal Food, Drug and Cosmetic Act
IMI	Innovative Medicines Initiative
IP	Intellectual Property
IPR	Intellectual Property Right
SME	Small and Medium Enterprises
SSNIP	Small but Significant and Non-transitory Increase in Price
TFEU	Treaty on the Functioning of the European Union
TTBER	Technology Transfer Block Exemption

A. Introduction

Parallel importation is a constantly growing form of trade. It occurs when the original goods protected by intellectual property rights (IPR) are put on the market by the manufacturer or with his consent in one country but then imported to another country by a parallel trader without the consent of the manufacturer, passing the authorized distributor. These goods are described as "parallel imports" or "grey market goods". Usually prices of the goods are lower in the first market and the parallel trader benefits from the price difference when selling the goods at a higher price in another country. This form of trade might reduce the income of manufacturers and official distributors which leads to the attempt to prevent parallel importation. Parallel importation is debated most in branded products market and especially in pharmaceutical industry which will be the focus of this study.

In the European Union (EU), admissibility of parallel imports is based on the principle of free movement of goods defined in the Treaty on the Functioning of the European Union (TFEU).[1] Although the owner of an IPR (a patent, a trademark, or copyright) would be able to use its monopoly position in order to prevent parallel trade, this conduct might in certain circumstances prove to be against the provisions of Competition law. Depending on the case, both Article 101 TFEU on prohibition of agreements which limit competition and Article 102 TFEU on abuse of dominant market position would be applicable. Distinctions between the interests of intellectual property (IP) owners and parallel traders in the light of EU competition rules are often complicated and may lead to disputes.

The interface of Competition law and IPR is contradictory due to the fact that IPRs create exclusive rights enabling the proprietor of such rights to strengthen his position on the markets and restrict competition. However, goals of IPRs and Competition law are to a large extent the same. Regulations in both laws aim at dynamic efficiency and economic welfare in general.[2]

---

[1] The Treaty on the Functioning of the European Union (TFEU), Consolidated Version 26 October 2012, OJ C-326/01

[2] K. Tervo, *EY:n kilpailuoikeuden soveltuvuus ETA:n ulkopuolelta tulevaan rinnakkaistuontiin in,* A. Saarnilehto (Ed.), Teollisoikeudellisia kirjoituksia VII, 123 at 123 (2006)

There are several specific national and EU regulations in the European pharmaceutical sector, due to which parallel trade is a controversial issue. Although the Community imposes certain obligations to pharmaceutical manufacturers, national authorities have the right to regulate the prices of pharmaceuticals. The price differentials created by Member States' individual price fixing boost parallel trade. Pharmaceutical manufacturers consider that price differences are generated by the lack of unity by governments, not by the actions of the industry itself. Therefore, manufacturers' economic interests should be protected by limiting parallel trade. However, in the Commission's view, restrictions to parallel trade would be inconsistent with the goal of market integration.[3]

The choice of strategies against parallel trade by companies operating in multiple countries is relevant to all IP-intensive industries. However, due to the particularities of the drug industry, such as the necessity of citizens' access to treatment, governmental price regulation and the importance of innovation, parallel trade is given a greater weight.[4] The effect of parallel trade in pharmaceuticals to consumer welfare through lower prices and to innovation has been studied both theoretically and empirically, and more evidence is being gathered concerning its impact in the EU.

Parallel trade seems to be a massive challenge to the profitability of pharmaceutical manufacturers since the research and development (R&D) suffers. This challenge gives rise to attempts of preventing parallel trade with various strategies, such as dual pricing and supply restrictions. On the other hand, other stakeholders (national health authorities, the Commission and parallel traders) argue for consumer benefits. The competing interests of stakeholders thus need balancing.

Parallel trade in pharmaceuticals has been justified by free movement of goods, promotion of common market and benefits to consumers. In the environment of free market, the pro-competitive free movement of goods creates benefits to the consumers by equalizing price differences. However, the pharmaceutical market makes an exception in the EU: it is not a free market but is distorted by various price regulations and controls by national authorities of Member States. In these circumstances, restrictions to parallel trade should be analyzed taking into account the

[3] A. Dawes, *Neither Head nor Tail: the Confused Application of EC Competition Law to the Pharmaceutical Sector*. European Competition Law Review, 27(5), 269 at 274-275 (2006)
[4] M. K. Kyle, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in*, B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 339 at 339 (2009)

specific characteristics of the sector. The impact of parallel trade on consumer welfare should be weighed against the special nature of the sector. The uncertainty of the Competition law issues on parallel trade in pharmaceuticals makes it a relevant and meaningful subject to study.

This thesis examines the special characteristics of the pharmaceutical industry in parallel trade cases under EU Competition law. For this purpose, I will focus on restrictions deriving from dual pricing schemes and a dominant undertaking's refusal to supply pharmaceuticals. I will try to answer the following questions: How the special nature of the pharmaceutical sector is being considered when assessing dual pricing under Article 101 TFEU and refusal to supply under Article 102 TFEU? What is the effect of parallel trade on pharmaceutical prices, on innovations, and on consumer welfare? And finally, taking into account the current legal and economic context of parallel trade, should the pharmaceutical sector be given a special position under Competition law?

This thesis is based on qualitative research. The main research methods are studies on literature and case law, as well as questionnaires to the European Commission DG officials and Finnish Competition and health authorities. These questionnaires show the current view of the Commission and Finnish authorities on the issues in this area and enable the analysis of the future implications of this subject. The questions and answers are included in Annex I and II. The research is accompanied with a comparative study on the approach to parallel trade in pharmaceuticals in the US and the EU.

The structure of the thesis is the following. Chapter A contains the introduction to the research, the aims and research questions and the methods used to complete this study. Chapter B examines the relationship between intellectual property rights and EU Competition policy in parallel trade, especially in pharmaceuticals. Chapter C introduces the European pharmaceutical market and the special features of the market. It will study the regulatory measures in the market and the importance of innovation in the industry. Chapter D includes a case study on parallel trade of pharmaceuticals in EU Competition law, more specifically how EU Competition law treats the strategies of dual pricing and refusal to supply as means of manufacturers to prevent parallel trade. Further, it will discuss how the special characteristics have been taken into account in the assessment under Competition law. Chapter E analyzes the economic effects of parallel trade on prices and on R&D in the light of the case law dealt in the previous chapter.

Chapter F compares the different approaches to parallel trade in pharmaceuticals in the EU and the United States. It tries to find out whether there is something to be learnt from each jurisdiction. Chapter G will present the current policy arguments by the European Commission authorities, specifically the authorities of DG Competition, and the Finnish Competition and Pharmaceutical authorities. The answers to the questionnaires will be reflected to the appropriate case law presented in the earlier chapters. Chapter H will provide an answer to the research questions and present a way forward in the current issue.

This study is limited to pharmaceuticals protected by patents; after the patent has expired, the biggest competition pressure moves to generic medicinal products which are outside the scope of this work. Free movement of goods and creation of an internal market as fundamental EU goals are discussed as far as they concern the intersection between IPRs and Competition law, particularly in regard to parallel imports of pharmaceuticals. This thesis will not cover the Intellectual Property Laws as such. Furthermore, the repackaging issues related closely to trade mark rights and exhaustion of IPRs are not in the focus of this work.

B. Parallel Trade within the EU

I. Introduction

The pharmaceutical sector and EU Competition law have been in a controversial position, not least due to the tension between the policy of the European Commission (hereinafter "the Commission"), encouraging parallel trade in the EU in order to strengthen a common market, and the belief of the manufacturers that parallel trade undermines stimulation to invest in R&D promoted by national governments.[5]

The basis of parallel trade lies on the EU principle of free movement of goods and the principle of Community exhaustion, which allows the IPR protected goods to circulate freely after their first marketing in the EEA[6]. These principles have been strictly enforced by the European Commission and the European Court of Justice (ECJ) against any restrictive measures from Member States or private entities concerning parallel trade. Consequently, these legal settings have enabled the growth of parallel trade.[7] One of the goals of the European Community has been to achieve a single market, which would not only need the removal of all barriers to trade between Member States, but also obstacles to trade imposed by operators able to create such barriers. The single market remains as a cornerstone of the European Union and Competition rules serve that objective by protecting the market economy and achieving market integration.[8]

Parallel imports are often seen as providing an arbitrage between the price levels in different national markets, and at the same time as a balancing instrument against the big suppliers and their distribution networks. The protection which parallel imports gets is an important part of the Community integration achievement. The Commission has expressed its view on parallel imports in the Communication of 2003[9] stating that parallel trade is a lawful form of trade within the

---

[5] A. Coscelli, G. Edwards & A. Overd, *Parallel trade in pharmaceuticals: more harm than good?* European Competition Law Review , 29(8), 490 at 490 (2008)

[6] EU Member States and EFTA counties Norway, Island and Liechtenstein are members of European Economic Area. Switzerland is an EFTA country, but is not belonging to EEA.

[7] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals:
The Case of Parallel Trade, 1-2 (2011)

[8] A. Montesa Lloreda, *Parallel Trade in the Pharmaceutical Industry from a Competition Point of View, in* H. Kanninen, N. Korjus & A. Rosas (Eds.), EU Competition Law in Context, 233 (2009)

[9] European Commission Communication on parallel import of proprietary medicinal products for which marketing authorisations have already been granted, COM (2003) 839 final, 30 December 2003

European Union and therefore supported. However, there have been critics towards parallel traders as 'free riders' who exploit the supplier's ready investments in brand and sales promotion, but do not need to carry responsibility for example for deliveries of the full range of products.[10]

The early case law shows that the effects of IPRs were a great concern to competition authorities. This resulted in too strict limits of the exercise of IPR. The economic understanding came later, where it was understood that the legal monopoly created by IPR does not necessary create economic power, but this should rather be established empirically. The European Courts started the work to balance the relationship between IPR's and Competition by interpreting the EU Treaty provisions. It resulted in the distinction between the 'existence' and the 'exercise' of IPRs. The concepts of 'specific subject matter' and the 'Community exhaustion' followed. Thus the current legal environment is supporting parallel trade. The Commission and EU Courts have treated any restrictions to parallel trade negatively. However, in recently this policy has been questioned in pharmaceutical cases, due to the different interpretations of welfare effects of parallel trade.[11]

II. Parallel Trade in Pharmaceuticals

Pharmaceutical industry can be divided into two divisions: research-based and generic pharmaceutical industries. The first mentioned focuses on research and development of new original drugs or existing treatments, while the latter concentrates on producing generic drugs equivalent to the original drugs after the patent protection for the original drug has ceased. [12]

Apart from these two industries, there exists an independent sector of parallel imports of medicinal products. Companies involved in parallel imports are not part of manufacturing of the drugs but mostly part of supply chain. [13] The costs of parallel importers involve primarily only costs related to the sales of the pharmaceuticals – they do not have any R&D expenses. In 2008, the estimated volume of the turnover of parallel imports of the European medicine markets was 2 - 3%, and there

[10] I. van Bael & J-F. Bellis, Competition Law of the European Community, 213 (2010)
[11] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 79-80 (2011)
[12] T. Aitlahti, *Lääkevalmisteiden dokumentaatiosuoja. Kannustin uusien lääkehoitojen kehittämiseen*, IPR Info 3/2005, at 10
[13] Communication from the Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, COM (2009) 0351 final, 43. The report presents parallel distributors as a part of supply chain together with wholesalers and pharmacies.

were about 100 enterprises in Europe involved in the business. Generally, companies involved in parallel trade, are SME companies.[14] The latest estimate on the volume of the parallel trade in pharmaceuticals was in 2011 €5,000 million (value at ex-factory prices).[15]

Price differences of genuine goods between markets encourage parallel importers to gain profits by buying the goods from a cheaper country and selling them again in a country with higher prices.[16] There are many reasons for the price differences to occur, such as currency fluctuation, price or product regulation, distribution costs and manufacturers' choice in pricing. According to the theory by Frank P. Ramsey (Ramsey Pricing)[17], raising the prices in inelastic markets is strategically wise due to the fact that the consumer would eventually have to buy the product.[18] Furthermore, the national price regulation is one of the major reasons for the parallel trade in pharmaceuticals. For example in Greece and Spain the governmental regulations for decreasing the prices of pharmaceuticals are strict, which has led to the situation that these countries are currently two of the main pharmaceutical export markets in the EU.[19]

Thus, parallel trade in pharmaceuticals is driven by the price differentials due to the manufacturers' pricing policies and governmental price controls. These differentials are up to 30 % and more, which creates a strong economic incentive for parallel traders.[20] The applicable approach of price strategies depends, for example, on whether Member State in question has research-based drug industry. Member States with high prices on pharmaceuticals, i.e. destination countries of parallel imports are particularly Denmark, the UK, Sweden, the Netherlands, Germany, Norway and

---

[14] J. Joukas, *Lääkevalmisteiden uudelleenpakkaaminen Euroopassa in* K. Sorvari (Ed.), Teollisoikeudellisia kirjoituksia XI, 25 at 33 (2010), see, Communication from the Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, COM (2009) 0351 final, 45

[15] Information available at http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf last revisited on 04 May 2014

[16] G. Grassie, *Parallel Imports and trade marks – where are we? Part 1*, European Intellectual Property Review 28(9), 474 at 474 (2006)

[17] Information available at http://isites.harvard.edu/fs/docs/icb.topic90998.files/ramsey-pricing.pdf (last revisited on 02 May 2014)

[18] I. Avgoustis, *Parallel imports and exhaustion of trade mark rights: should steps be taken towards an international exhaustion regime?* European Intellectual Property Review, 34(2), 108 at 109 (2012)

[19] A. Feros, *Free movement of pharmaceuticals within the EU - should rights be exhausted regionally?* European Intellectual Property Review, 32(10), 486 at 489 (2010)

[20] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 45-46 (2011)

Finland. Low price Member States, i.e. source countries of products are Greece, Spain, Portugal, Italy, and France.[21]

By some estimates, parallel trade is amounted up to 5% of drug sales in Europe, but it is difficult to quantify the money lost by the manufacturers as a result of parallel trade. According to a study carried out by the Economic and Social Research Council in 2004, parallel trade caused a loss of £770 million for pharmaceutical manufacturers only in the UK. These numbers might explain the fierce fight of the manufacturers against parallel trade.[22] Thus, pharmaceutical manufacturers are constantly trying to limit parallel trade by placing a number of strategies such as export bans, dual pricing, limits to supply and use of IPRs to divide the markets.[23]

III. Internal Market and the Exhaustion Principle

1. Free Movement of Goods

Creation of a single market without barriers was one of the first aims of the European Union. Internal barriers to trade are eliminated by the principle of free movement of goods, according to which Member States should not impose any barriers or restrictions to trade.[24] Parallel trade is justified by Articles 34 and 35 TFEU, according to which quantitative restrictions of import and export of goods between the Member States and of all other measures having equivalent effect are prohibited. Article 36 TFEU defines exceptions to the main rule, stating that the provisions of Articles 34 and 35 "shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property".

---

[21] P. Kanavos & J. Costa-i-Font, *Pharmaceutical parallel trade in Europe: stakeholder and competition effects*. Economic Policy, 751 at 762, 767 (2005)
[22] A. Montesa Lloreda, *Parallel Trade in the Pharmaceutical Industry from a Competition Point of View, in* H. Kanninen, N. Korjus & A. Rosas (Eds.), EU Competition Law in Context, 234 (2009)
[23] ibid at 236
[24] I. Avgoustis, *Parallel imports and exhaustion of trade mark rights: should steps be taken towards an international exhaustion regime?* European Intellectual Property Review 34(2), 108 at 112 (2012)

However, such prohibitions or restrictions shall not serve as a tool for arbitrary discrimination or hidden limitations of trade between the Member States.[25]

The establishment of a single market and protection of national interests in intellectual property have created a conflict, which has required a strong reconciliation from the ECJ. In comparison with the competition rules of TFEU, described above, Articles 101 and 102 (former Articles 81 and 82 EC) do not provide such a balance, but the reconciling role of competition law and intellectual property has been on the agenda of the EU courts trying to find the balance case by case.[26] As stated earlier, Article 36 TFEU is an exception to the main rule of free movement, and the protection of industrial and commercial property has been invoked in cases where the IP owners have tried to prevent parallel trade. However, this exception can impair the function of the single market; therefore the interpretation of this rule by the ECJ has been quite narrow.[27]

The integration of intellectual property rights on free movement of goods started from case *Consten and Grundig*[28]. The ECJ has successfully eliminated restrictions created by IPRs on free movement of goods. This jurisprudence has been refined concerning the cases of the exhaustion principle. The aim is to balance free movement of goods and the interests of IPR owners.[29]

Case *Consten and Grundig* in 1966 was the beginning of the development of the Community-wide exhaustion although the principle was only implicit in the judgment. Grundig allowed Consten to register a second trade mark in Consten's name so that it could use the trade mark to prevent parallel imports of Grundig products from Germany. The agreement constituted a breach of competition law, namely Article 81(1) EC (now Article 101(1) TFEU). The Court stated: "Since the agreement thus aims at isolating the French market for Grundig products and maintaining artificially, for products of a very well-known brand, separate national markets within the

[25] The Treaty on the Functioning of the European Union (TFEU), Consolidated Version 26 October 2012, OJ C-326/01
[26] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 90-91 (2011)
[27] I. Avgoustis , *Parallel imports and exhaustion of trade mark rights: should steps be taken towards an international exhaustion regime?* European Intellectual Property Review, 34(2), 108 at 112 (2012)
[28] Judgment of 16 July 1966 in *Joined Cases 56/64 and 58/64, Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v. Commission (Consten and Grundig)*, [1966] ECR 299
[29] S. Enchelmaier, *The inexhaustible question - free movement of goods and intellectual property in the European Court of Justice's case law, 2002-2006*, International Review of Intellectual Property and Competition Law, 38(4), 453 at 453 (2007)

Community, it is therefore such as to distort competition in the Common Market"[30] The judgment gave the same reasoning on which the exhaustion principle is based, the isolation of markets would distort free movement of goods.[31] The general concept of exhaustion was introduced in this case.

2. Exhaustion of Intellectual Property Rights

In the conflict between IPRs and Competition law, one goal is to promote competition by penalizing the distortions of market. Another goal is to promote innovation and proprietary rights. Intellectual property is protected by Article 345 TFEU, which states "…[t]his Treaty shall in no way prejudice the rules in Member States governing the system of property ownership".[32]

The intellectual property rights are exhausted after the goods protected by IPR are put on the market for the first time. The purpose of the exhaustion principle is to prevent the use of exclusive rights to partition the market. Therefore the geographical market to be protected needs to be defined. There are different forms of exhaustion regimes: national, regional and international. Under national exhaustion the rights will be exhausted only if the goods are sold for the first time in that particular country. If the products are put on the market outside that country, the intellectual property owner has the right to prevent the parallel imports. The United States apply this regime for patents. Applying the international exhaustion regime means that the rights are exhausted after the goods are put on the market of any country and the intellectual property owner cannot prevent the parallel imports. The US applies this regime to trade marks. The regional exhaustion means that the rights are exhausted when the goods are put on the market inside that region. The parallel imports can be blocked from outside the region. The European Union applies this system, called the "Community exhaustion"[33], which will be discussed below in detail.

Decisions by the ECJ during the last decades have established a regime of "Community exhaustion" of IP rights, including patents, trademarks and copyrights. Pharmaceuticals are usually protected by patents and trademarks. In a number of cases, where courts have recognized that these

[30] Joined Cases 56/64 & 58/64, Consten and Grundig, at 343
[31] D. T. Keeling, Intellectual Property Rights in EU Law: Volume 1: Free Movement and Competition Law, 80-81 (2003)
[32] T. Hays, Parallel Importation under European Union Law 115 (2004), *see also* Article 345 TFEU
[33] C. Stothers, Parallel Trade in Europe: Intellectual Property, Competition and Regulatory Law, 40-43 (2007)

rights are valid by national legislation and enjoy protection by exception of Article 36 TFEU, the exercise of the IPR has been examined under Article 34 TFEU stating that these rights shall not prevent free movement of goods. This doctrine of exhaustion was first ruled by the ECJ in case *Deutsche Grammophon*.[34] The Court established the principle of Community exhaustion for the first time, where it stated that: "It would be in conflict with the provisions prescribing the free movement of products within the common market for a manufacturer of sound recordings to exercise the exclusive right to distribute the protected articles, conferred upon him by the legislation of a Member State, in such a way as to prohibit the sale in that State of products placed on the market by him or with his consent in another Member State solely because such distribution did not occur within the territory of the first Member State."[35]

The same reasoning was subsequently used in regard to patents in *Centrafarm v. Sterling Drug*[36], in regard to trademarks in *Centrafarm v. Winthorp*[37] and later in *Centrafarm v. American Home Products*[38]. This principle was also applied to several cases where IPR holders tried to use their IP rights in order to prevent repackaging of goods. The Court decisions clearly stated that after the IP rights have been exhausted, it is prohibited to stop parallel trade once the product has been legally put on the market in another Member State by the IPR owner, his licensee, or a person dependent on the IPR owner. [39]

In December 1988, the Trade Mark Directive was adopted to harmonize the laws of Member States regarding trade mark legislation. According to Article 7, paragraph 1 of the TM Directive **"**The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent". According to the same Article 7, paragraph 2, "Paragraph 1 shall not apply where there exist

[34] L. Hancher & W. Sauter, EU Competition and Internal Market Law in the Health Care Sector, 112 (2012) *see also*, Judgment on 8 June 1971 in *Case C-78/70 Deutsche Grammophon Geschellschaftmb H v. Metro-SB-Grossmärkte GmBH&Co.KG (Deutsche Grammophon*, [1971] ECR 487, para 6
[35] *Case C-78/70 Deutsche Grammophon*, para 13
[36] Judgment of 31 October 1974 in *Case C-15/74 Centrafarm BV et Adriaan de Peijper v. Sterling Drug* Inc. *(Centrafarm v Sterling Drug)*, [1974] ECR 1147
[37] Judgment of 31 October 1974 in *Case C-16/74 Centrafarm BV et Adriaan de Peijper v. Winthrop BV (Centrafarm v Winthorp)[*1974] ECR 1183
[38] Judgment of 10 October 1978 in *Case C-3/78, Centrafarm BV v. American Home Products Corp. (Centrafarm v American Home Products)* [1979]
ECR 1823
[39] L. Hancher & W. Sauter, EU Competition and Internal Market Law in the Health Care Sector, 112 (2012)

legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market".[40]

In *Merck v. Primecrown*[41], the Court had to answer the question, whether price regulation of pharmaceuticals and expired patent protection would justify not applying the regional exhaustion of IPRs.[42] This was the first time the special nature of the pharmaceutical sector was discussed.

Price regulation was regarded not to justify the deviation from the regional exhaustion rule. In fact, AG Fennelly argued that a patent right does not justify a monopolistic profit, alleging explicitly that "the fact that the application of such price controls may, along with various other factors, affect the potential profits of pharmaceutical patentees is not relevant for the interpretation of the balance between the free movement of pharmaceutical products and the protection of national patent rights."[43] The Court agreed on this point with AG Fennelly's opinion. Thus, it confirmed previous rulings where price differences and non-harmonized price controls in the pharmaceutical sector are not relevant when assessing whether restrictions to exports are anti-competitive.[44]

3. Competition Law and Intellectual Property in the Internal Market

Competition law has an ability to regulate the exercise of IPR's. The recent cases in the pharmaceutical industry show that the reach of competition law has expanded further. Competition rules have developed to a second level of IP regulation, which concerns anti-competitive conduct unregulated by the IP legislation. It has been argued that IPR legislation and Competition law

[40] First Council Directive 89/104/EC of 21 December 1988 to approximate the laws of the Member States relating to trade marks [1989] OJ L 159/60; now enacted as Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trade marks (Codified version), [2008] OJ L 299/25 (Trademark Directive)

[41] Judgment of 5 December 1996 in *Joined Cases C-267/95 and C-268/95 Merck & Co. Inc., Merck Sharp et Dohme Ltd and Merck Sharp Dohme Int. Services BV v. Primecrown Ltd et al.* [1996] ECR I-6285 *(Merck v Primecrown)*

[42] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 148 (2011)

[43] Advocate General Fennelly in *Joined Cases C-267/95 and C-268/95, Merck v. Primecrown*, [1996] ECR I-6285, para 163; C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 148-149 (2011)

[44] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals:
The Case of Parallel Trade, 149 (2011) *see also, Joined Cases C-267/95 and C-268/95 Merck v. Primecrown*, para 47 and *Case C-15/74 Centrafarm v. Sterling Drug*

should be equal under EU law, or that Competition law should give way to IPR legislation in the name of innovation, since IPRs provide major incentives to innovators.[45]

Effective or workable competition means that companies are subject to reasonable constraints to competition, from competitors and customers, and that competition authorities ensure such constraints exist on the market.[46] EU competition policy appears to be based on the idea of effective competition with the goal of maintaining it within the single market.[47] It has also been argued that minor price competition is first of all a result of strategic behavior of the manufacturing pharmaceutical industry, aiming at reduction of parallel imports.[48] Based on these arguments, the efforts of the Commission to support parallel imports seem quite logical.

Generally IPRs and Competition law have the same goal: consumer welfare and innovation. However, the means differ. Intellectual property law offers exclusive rights for the encouragement of innovation through a monetary compensation, whereas competition law promotes innovation through the free market access and prevention of foreclosure.[49] IPRs are monopolistic in their nature, since they give their owners a possibility to prevent competitors from using the same inventions and brands. This has an effect to hinder or diminish competition. As a result, the owners of IPR can place higher prices for the goods. This creates a conflict between IPR and Competition law.[50] There are opinions stating that IP law itself would balance the incentive and innovation needs with market access. One could though oppose this for the reasons that IP legislation cannot regulate issues of competition law.

The search for the balance between competition law and IPRs has been ongoing for over forty years by the European institutions. The first case, where the application of the Article 101 TFEU to an agreement to restrict parallel imports was considered, was *Consten and Grundig*[51]. The case

[45] S. Anderman & H. Schmidt, EU Competition Law and Intellectual Property Rights: The Regulation of Innovation 3-4 (2011)
[46] C. Waelde, Contemporary Intellectual Property Law and Policy 869-870 (2014); *see also* R. Whish and D. Bailey, Competition law, note 2, 18 (2012)
[47] C. Waelde, Contemporary Intellectual Property Law and Policy 869-870 (2014); *see also* W.R Cornish, D Llewelyn and T Aplin, Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights, paras 1-39 – 1-47 (2010)
[48] M.K. Kyle, Strategic Responses to Parallel Trade, NBER Working Paper, 24
[49] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 79 (2011)
[50] T. Hays, Parallel Importation under European Union Law 114 (2004)
[51] *Joined Cases C-56/64 & C-58/64, Consten and Grundig*

law of the European Courts and the Commission's decisions show that the focus has been on protection of so called intra-brand competition, not inter-brand.[52] Thus, restrictions on intra-brand competition have regularly been disapproved, even in situations where a potential increase of competition between the brands would have been apparent, even sometimes preventing a new product from entering the market. This priority shows the importance of EU internal market, driven both by the Commission and the Courts.[53]

EU Competition law is not as such restricting the use of IPR, only where the circumstances of the use or licensing of IPR becomes so extraordinary that the underlying policy of the grant of these rights is threatened, Competition law determines whether there is a violation.[54] Article 101 TFEU prohibits agreements which may affect trade between Member States with an object or effect of preventing, restricting or distorting competition in the common market. Article 102 of TFEU prohibits abuse of a dominant position by undertakings, which may affect trade between Member States.[55]

The ECJ drew distinction between the existence and exercise of IPRs in *Consten & Grundig* and provided that the use of IP could be infringing Article 101, if the distributor would enjoy absolute territorial protection.[56] However, the Court changed its policy in *Maize Seeds*[57], where the vertical exclusive licenses were assessed to be pro-competitive. This change culminated to the Technology Transfer Block Exemption (TTBER) in 1996. Today, the main element of regulating the licensing is the new TTBER from 2004 and the guidelines, which have taken more economic approach.[58] The ECJ has regularly pointed out that in order to establish an abusive conduct corresponding to the exercise of IPR there has to be some 'additional factors' or 'exceptional circumstances' for the elimination of competition. However, it has held that in the conflict situation, the exercise of IPR should yield to competition law.[59]

---

[52] Inter-brand competition occurs between different substitutable products, whereas intra-brand competition occurs between the same pharmaceutical products.
[53] I. van Bael & J-F. Bellis, Competition Law of the European Community, 211 (2010)
[54] G. Tritton, Intellectual Property in Europe, 2008, 751
[55] Treaty on the Functioning of the European Union (TFEU), OJ C 326, 26.10.2012
[56] R. Whish, Competition Law, 763 (2009)
[57] Judgment of 8 June 1982 in *Case C-258/78, L.C. Nungesser and Kurt Eisele v Commission (Maize Seeds*) [1982] ECR 2015
[58] S. Anderman, *The new EC competition law framework for technology transfer and IP licensing*, Research handbook on intellectual property and competition law in Drexl, J. (Ed.), 109 at 109-110 (2008)
[59] S. Anderman, H. Schmidt, EU Competition law and Intellectual Property Rights – The Regulation of Innovation, 18-19 (2011)

In *Parke-Davis*[60], the ECJ established that the mere use of IPR does not conflict with Competition law, however certain abusive use can violate competition. This requires finding an additional element to the normal exercise.[61] The permitted exercise of the IPR was tested in *Hoffman-La Roche*[62], where the Court concluded that if the trade mark has not been used as a tool for the abuse of a dominant position, the exercise of the trade mark is lawful although the undertaking has a dominant position. In *Volvo* the Court declared that under Article 102 the refusal to grant a license does not itself constitute an abuse of a dominant position. [63] The Court confirmed this position in *Magill* and *IMS Health*, stating however that the exercise of the IPR might in exceptional circumstances be abusive.[64]

IV. Restrictions to Pharmaceutical Parallel Trade

The players of the pharmaceutical industry, i.e. the manufacturers and parallel importers, have ended up in several disputes resolved through settlements or court trials. The original producers have been claimed for hindering the entry of parallel imported products into the market. Also some differences in the aims of IPRs and Competition law have resulted in legal actions. Both the arguments of the decisions and defence statements have included different opinions, first, on the nature of the pharmaceutical sector deviating from other industries because of regulation, R&D expenses and safety of medicines and, secondly, on the acceptability of restricting parallel imports of pharmaceuticals.[65]

Pharmaceutical companies have presented a view that the unstable activities of the parallel traders create demand unpredictability and supply chain problems leading to allocation inefficiencies so that manufacturers might not meet the required stock levels needed for consumers in Member States. Consequently, they have introduced different dual pricing strategies to reduce the price

---

[60] Judgment of the Court on 29 February 1968 in *Case C-24/67, Parke Davis and Co. v Probel*
[61] A. Kur & T. Dreier, European Intellectual Property Law: Text, Cases & Materials, 395 (2013)
[62] Judgment of 23 May 1978 in Case C-102/77 *Hoffman- La Roche et Co v. Centrafarm Vertriebsgesellschaft Pharmaceuticher Erzeugnisse MBH (Hoffman- La Roche)* [1978] ECR 1193, para 16
[63] Judgment of the Court on 5 October 1988 in *Case C-238/87 Volvo AB v. Erik Veng Ltd (Volvo)[1988] ECR 6211,* para 11
[64] Judgment of the Court on 6 April 1995 in *Joined Cases C-241-242/91P, Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v. Commission (Magill),* [1995] ECR I-743, para 50; and Judgment of the Court on 29 April 2004 in *Case C-418/01, IMS Health GmbH & Co. V. NDC Health GmbH & Co.,* [2004] ECR I-5039
[65] L. Hancher, *The EU pharmaceuticals market: parameters and pathways in* Mossialos, E. (Ed.), Health Systems Governance in Europe: The Role of European Union Law and Policy, 635 at 662 (2010)

differentials between markets which would reduce the incentive for parallel trade. Another strategy is the supply quota system, which usually restricts supplies to wholesalers. In terms of Competition law, supply quotas may breach Article 101(1) TFEU if the manufacturer has made an agreement with the wholesalers. Otherwise it might only be caught if the manufacturer has a dominant position on the market. Dual pricing might be considered as breach of Article 101 TFEU, if there is an agreement, or Article 102 TFEU, if the supplier is dominant on the market. However, under certain conditions, both of these strategies might be exercised.[66]

Competition policy pursues several objectives. Firstly, enhancement of efficiency; secondly, the protection of consumers and; thirdly, creation of a single market. However, these objectives have not remained stable over time.[67] The Commission Guidelines on Article 101(3) state that the goal of EU competition rules is to protect competition in order to enhance welfare of consumers and secure efficient resource allocation. Agreements restricting competition may have efficiency benefits which promote competition. Such efficiencies may result in additional value by means of lower production costs, better quality or innovation of new products. If such agreements' net effect promotes competition through better goods and better prices to the customers, i.e. pro-competitive economic effects outweigh anti-competitive effects, they meet the objectives of the EU competition rules.[68]

The case law other than in pharmaceutical sector show that agreements aiming at prohibiting parallel trade have been regarded as having the object the prevention and the restriction of competition, thus breaching Article 101(1) TFEU. The practices that a dominant undertaking might apply in order to prohibit parallel trade, such as a refusal to supply, have generally been caught by Article 102 TFEU if they are not objectively justifiable.[69]

---

[66] L. Hancher, *The EU pharmaceuticals market: parameters and pathways in* Mossialos, E. (Ed.), Health Systems Governance in Europe: The Role of European Union Law and Policy, 635 at 662-663 (2010) *see also, Joined Cases* C-2/01 P and C-3/01 P, *BAI and Commission v. Bayer* [2004] ECR I-23; Case T-41/96 *Bayer v. Commission* [2000] ECR II-3383; Case T-168/01, *GlaxoSmithKline Services v. Commission* [2006] ECR II-2969

[67] P. Graig, G. de Búrca, EU Law: Text, Cases and Materials, 959-960 (2011)

[68] EU Commission Guidelines on the Application of Article 81(3) of the EC Treaty (now 101(3) TFEU) of 27 April 2004, OJ C/101, para 33

[69] L. Grigoriadis, *Application of EU Competition Law in the Pharmaceutical Sector: the Case of Parallel Trade*, European Business Law Review 25(1), 141 at 144 (2014); *see also, Joined Cases C–56/ & C–58/64, Consten and Grundig; Case C-19/77, Miller v. Commission, [1978] E.C.R. 131; Joined Cases C-32/78, C-36/78; C-82/78, BMW Belgium SA and others v. Commission*,[1979] ECR 2435; Case C-551/03, General Motors BV v. Commission, [2006] ECR I-3173

Although the restrictions to parallel trade in other sectors have generally been regarded restrictive, the pharmaceutical sector might need special treatment due to its special nature. The arguments to prefer the special treatment are based on several factors: the strict regulation of prices in the pharmaceutical sector, the impact of parallel trade to the innovation incentives of the pharmaceutical manufacturers, and the effect of parallel trade on consumers and social health care funds.[70]

The first case where the Commission expressed its view on the pressure of the manufacturers of pharmaceutical sector on their dealers was *Sandoz*[71]. Both the ECJ and the Commission regarded the behaviour of Sandoz as an attempt to reduce parallel exports from Italy to other Member States through arrangements with wholesalers. According to the ECJ, this constituted an agreement which is prohibited by Article 101(1) TFEU.[72] The special characteristics of the pharmaceutical sector in relation to parallel trade were not an issue at that time and accordingly, the EU Courts considered this only in latter cases.[73]

In *Bayer*[74] (Adalat), the ECJ did not take a stand on the matter whether the practice between a drug producer and wholesalers of supply limitations was a breach of EU competition legislation as it considered that unilateral supply restrictions by the drug producer did not constitute an agreement between the producer and its distributors. The case might have been in the Commission's view a defeat concerning its policy towards companies trying to prevent parallel trade. This case was a victory for the pharmaceutical manufacturers, but a discouraging precedent for the parallel traders. It can be said based on this judgment that manufacturers, in order not be caught by Article 101, should set unilateral measures and avoid any indications of an invitation to confederate. Limitations of supply by a non-dominant player in this case proved not to be breaching competition law, but monitoring and sanctioning policies might be dangerous in that regard.[75]

---

[70] L. Grigoriadis, *Application of EU Competition Law in the Pharmaceutical Sector: the Case of Parallel Trade*, European Business Law Review 25(1), 141 at 144 (2014)
[71] Judgment of the Court on 11 January 1990 in *Case C-277/87 Sandoz prodotti Farmaceutici SpA v. Commission (Sandoz)*, [1990] ECR I-45
[72] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 130-131 (2011)
[73] A. Montesa Lloreda, *Parallel Trade in the Pharmaceutical Industry from a Competition Point of View, in* H. Kanninen, N. Korjus, A. Rosas (Ed.), EU Competition Law in Context, 239 (2009)
[74] Judgment of the Court on 6 January 2004 in *Joined Cases C-2/01 P and C-3/01 P, BAI and Commission v. Bayer [2004] ECR I-23*
[75] A. Montesa Lloreda, *Parallel Trade in the Pharmaceutical Industry from a Competition Point of View, in* H. Kanninen, N. Korjus, A. Rosas (Ed.), EU Competition Law in Context, 244-245 (2009)

It can be concluded that the more economic approach started from the *Bayer (Adalat)* case, when both the CFI and ECJ qualified the restrictions by Bayer more like unilateral conduct than an export ban, which would fall within the scope of Article 101 TFEU. They implicitly ruled favourably towards Bayer's quantity restrictions.[76] The risk of examining the limitation of supply through Article 102 TFEU might have pushed the manufacturers to try other means, such as dual pricing.[77]

A significant EU-wide precedent regarding supply restrictions, potentially limiting parallel trade, was the preliminary ruling by the ECJ in *Sot Lelos*[78] in 2008. It concerned the abuse of a dominant market position, caused by restrictions on supplies to wholesalers dealing with parallel exports. However, the Court established that even a supplier with a dominant market position may refuse to supply a wholesaler with an order which is not ordinary, even though the refusal is clearly aimed at restricting parallel trade. On the other hand, in the case of an ordinary order, a drug company holding a dominant position cannot refuse to supply for the reason that the wholesaler plans to take the products to other Member States. While the refusal to supply with ordinary drug orders was regarded as an abuse of a dominant position, the decision does not entirely prohibit supply limitations as an abuse of dominance.[79]

In *GSK v Commission*[80], restrictions to parallel trade in pharmaceuticals were clarified, particularly in regard to so called dual pricing systems. GSK charged different prices from the wholesalers depending on the final destination of the product. If the product was meant for use in Spain, a lower price applied; if it was meant for exports, a higher price was charged. Several wholesalers and their organizations complained about this practice to the Commission. In May 2001, the Commission made a decision stating that GSK's procedure constituted a contractual arrangement aimed at blocking parallel imports and thus breached Article 81 EC (now 101 TFEU). However,

---

[76] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 137 (2011)
[77] A. Montesa Lloreda, *Parallel Trade in the Pharmaceutical Industry from a Competition Point of View, in* H. Kanninen, N. Korjus, A. Rosas (Ed.), EU Competition Law in Context, 245 (2009)
[78] Judgment of the Court on 16 September 2008 in *Joined Cases C-468/06 to C-478/06 Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline AEVE Farmakeftikon Proionton*, formerly Glaxowellcome AEVE *(Sot Lelos)*, ECR 2008 I-07139
[79] A. Ezrachi, EU Competition Law: An Analytical Guide to the Leading Cases, 246-248, (2012)
[80] Judgment of the Court on 6 October 2009 in *Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P GlaxoSmithKline v. Commission GlaxoSmithKline Services Unlimited v. Commission of the European Communities* (Glaxo)[2009] E.C.R. I-9291

the ECJ came to a different conclusion than the Commission, as the Commission had not presented sufficient arguments of the negative consequences of the practice and had not investigated closely enough the potential efficiency benefits of the practice meant by the exemption under Article 81(3) (now 101(3) TFEU).[81]

Restrictions to parallel trade by dominant companies may fall under Article 102 TFEU. In order to identify the competitive restrictions towards the undertaking in question and whether the dominant position exists, it is necessary to define the relevant product and geographic market.[82] The definition of a relevant market helps to establish the boundaries of the competitive restrictions.[83] The ECJ has stated in *Continental Can* that: "… [t]he definition of the relevant market is of essential significance, for the possibilities of competition can only be judged in relation to those characteristics of the products in question by virtue of which those products are particularly apt to satisfy an inelastic need and are only to a limited extent interchangeable with other products."[84]

The products or services substitutable or interchangeable with the product in question define the relevant product market.[85] The ECJ held in *Hoffman-La Roche*: "The concept of the relevant market in fact implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned"[86] The objective characteristics which meet the consumer needs and competition conditions as well as the structure of supply and demand are considered. The boundaries of the market are often determined with the SSNIP test[87].

---

[81] C. Petrucci, *Parallel trade of pharmaceutical products: the ECJ finally speaks - comment on GlaxoSmithKline*, European Law Review 35(2), 275 at 275-276 (2010)
[82] J. D. C. Turner, Intellectual Property and EU Competition Law, 80 (2010)
[83] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 54 (2011)
[84] Judgment of 21 February 1973 in *Case C-6/72 Europemballage Corporation and Continental Can Company Inc. v Commission, (Continental Can)* ECR 215, para 32
[85] The Commission defines the relevant *product* market as follows: "A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use". See, Notice on the definition of the relevant market for the purposes of Community competition law [1997] OJ C372/5, para 7
[86] *Case 85/76 Hoffmann-La Roche v. Commission*, para 28
[87] I.e. Small but Significant and Non-transitory Increase in Price; The SSNIP test is a hypothetical price increase test, which consists a small (5% to 10%) but permanent change in prices. This change is analysed in the sense that whether the consumers would switch to other substitute products. If the price increase is not profitable due to the loss of sales as a result of the substitution, these additional substitute products

Defining the relevant market is not straightforward in the pharmaceutical sector, which has been recognized in the economic and legal literature. The differences in the characteristics of drugs, price controls and limited consumer choice explain the difficulty to use the SSNIP test in a traditional manner to the pharmaceutical market.[88] Therefore, under EU competition law, the definition of the relevant product market of pharmaceuticals is made according to the ATC (Anatomical Therapeutic Classification) system.[89] The pharmaceutical products are classified under five different groups on the basis of the organs or systems on which they act and the chemical, pharmacological and therapeutic properties.[90]

The ATC classification is used in a number of merger decisions, however it has not been dealt under the 102 TFEU before the *AstraZeneca*[91] case. The company was found to be dominant on the proton pump inhibitors market with the product 'Losec', which contains omeprazole. The Commission first analysed the ATC 3 level, which included 'H2 blockers'[92], but then narrowed the market to the mere omeprazole.[93] The change in the market definition was one of the main impacts of this case. Commission chose to highlight the mode of action rather than the therapeutic use. Losec (a proton pump inhibitor) and H2 blockers worked in a totally different way, so they were put into different markets even though they have previously treated similar problems. This suggests that an undertaking with a patent protected pharmaceutical product which uses a new biochemical action could be likely to be considered having market power at least according to the Commission.[94]

include to the relevant market. See in this effect: C. Degosus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 57 (2011)

[88] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 60-61 (2011)

[89] The ATC system was developed by the European Pharmaceutical Market Research Association (EPhMRA).

[90] F. Liberatore, UK calls for ban of parallel trade of prescription medicines - what are the EU competition law implications?, ECLR, 189 at 191 (2013)

[91] Judgment of the Court on 6 December 2012 in *Case C-457/10 AstraZeneca v. Commission (AstraZeneca)* [2013] 4 C.M.L.R

[92] H2 blockers were used for the treatment of peptic ulcers before the omeprazole

[93] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 69 (2011)

[94] M. Cole, *Pharmaceuticals and competition: first strike to the Commission?* E.C.L.R. 34(5), 227 at 230 (2013)

However, parallel trade is not concerned with inter-brand competition i.e. competition between different substitutable products, but the cases in parallel trade concern the trade of the same pharmaceutical product (so-called intra-brand competition). Therefore, the General Court noted in *GlaxoSmithKline* that accepting that all the drugs capable of being parallel imported in a certain Member State would constitute a product market, is not totally incorrect.[95]

V. Conclusions

In the EU, parallel imports of pharmaceuticals flourish due to encouragement from the Commission and the Courts, referring to the principle of free movement of goods and creation of a single market through the exhaustion principle. In contrast, pharmaceutical companies consider that parallel imports diminish their ability to invest in R&D due to lower returns. Parallel traders have been claimed to be 'free riders' as they exploit original drug companies' ready investments without being responsible, e.g. for coverage of supplies. Thus, these companies search for legal grounds to prevent parallel imports of their original products.

The promotion of a single market on one hand, and protection of IPRs, on the other hand, has created contradictory interests, requiring reconciliation by the ECJ. The search for finding a balance between these interests has been going on for decades through the harmonization attempts by the Commission and trough interpretative work of the EU Courts. From *Consten & Grundig*, the EU Courts have distinguished the existence and exercise of an IPR. Therefore, the mere existence of an IPR as such is not anticompetitive; only the exercise of an IPR as means for restriction of competition might prove to be against Competition law.

In the pharmaceutical industry, IPR is a vital part of the business and thus companies aim at larger market powers with the help of patents. Traditionally, all artificial restrictions to parallel trade have been considered as a severe breach of competition, which have not been exempted on efficiency grounds under Article 101(3) TFEU. Recent case law in the pharmaceutical sector, however, have shown light towards an economic approach which takes into account the special characteristics of the pharmaceutical industry and the economic impact of parallel trade. It is

[95]F. Liberatore, UK calls for ban of parallel trade of prescription medicines - what are the EU competition law implications?, ECLR, 189 at 191 (2013), *see also* Case T-168/01 - *GlaxoSmithKline Services v. Commission*, [2006] 5 C.M.L.R., para 159

though questionable whether the economic approach can be promoted in Competition law. These issues are discussed in more detail in subsequent chapters.

C. The Specific Features of the European Pharmaceutical Market

I. Introduction

Pharmaceuticals are essential for the modern society, since they preserve health, treat diseases and are also very cost-effective comparing to surgical proceedings. Pharmaceuticals, however, account a great proportion of governments' health expenditures. The public and regulators have claimed that drugs are too expensive which might impair patients' access to medicines and therefore limit their right to health. Governments have created different policy tools to control excessive prices. These price differences have created a favourable environment for parallel traders of pharmaceuticals.[96]

Pharmaceutical research has in the last thirty years created a health revolution, which can be seen in more effective drugs increasing life expectancy and the quality of life. Drugs treat many diseases and conditions supplementing nutrition, sanitation and medical care. Pharmaceutical business is one of the most profitable in the world. Pharmaceutical industry is global; however, the largest companies are located in North America, Europe and Japan which are often called as 'big pharma'. While the market is dominated by this 'big pharma', generally pharmaceutical industry can be considered dynamic, with a good level of entry of new firms. The market has become more concentrated after the wave of mergers in the 1990s, therefore drugs are sold by fewer firms. This has a negative impact on the degree of competition.[97]

The EU pharmaceutical policy has as its objectives to ensure a high level of innovation and to secure public health as well as to provide a competitive industry of pharmaceuticals. Medicines should be safe and effective and access to medicines should be affordable. Although the European Medicines Agency (EMA)[98] has legislative powers in pharmaceutical licensing and marketing, it has less influence on prices and purchasing of drugs. The role of Member States is crucial in that aspect in spite of secondary legislation approved at the EU level, which is forming the market paths. National price and profit controls have also an impact on the competitiveness of the industry.

---

[96] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 1 (2011)
[97] Ibid at 12-14
[98] Information available online at – http://www.ema.europa.eu/ema/ last visited on 4 May 2014

These controls have often claimed to be one of the major factors for the difference of the European research industry compared to that of the US.[99]

The TFEU protects free movement of goods, which shall guarantee access to pharmaceuticals and other medical products on national markets. EU secondary legislation gives guidance on sales authorization of most of these products, and Member States are not entitled to block the trade through their own legislation with the aim of protecting public health.[100] However, not all the products are under this guidance and national price regulation is still legitimate. Moreover, pharmaceutical regulation is weakly harmonized, especially in regard to price and profit control. In addition, IPRs impact on the partitioning of the regions into separate national markets.[101]

This Chapter examines the specific features of the pharmaceutical industry at the EU level. In order to be able to analyze competition matters related to blocking of parallel imports, it is highly important to first investigate the characteristics which make pharmaceutical industry special from the Competition law point of view.

II. Regulation in the Pharmaceutical Market

1. Competence in Public Health

In accordance with Article 168 TFEU, as a horizontal objective, human health has to be protected and ensured on the highest level in all policies and activities of the EU. However, its paragraph 7 imposes a limit on the EU activities in the area of public health stating that Member States shall carry full responsibility for the organization of health and medical care. Thus, the EU's role is limited to encourage Member States to mutual cooperation, give support by request and complement national policies. This kind of share of competences in the health care issues means that price differentials caused by national regulation are fully legitimate according to the TFEU

[99] L. Hancher, *The EU pharmaceuticals market: parameters and pathways in* Mossialos, E. (Ed.), Health Systems Governance in Europe: The Role of European Union Law and Policy, 635 at 635-636 (2010)
[100] Council directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8
[101] L. Hancher & W. Sauter, EU Competition and Internal Market Law in the Health Care Sector, 110-111 (2012)

provisions.[102] As the pricing and reimbursement systems of the pharmaceuticals are determined solely by the Member States, harmonization is limited to the provisions of the Transparency directive[103] and the Directive of Medicinal Products for Human Use[104].

2. Obligation to Supply Medicines

According to Community legislation, pharmaceutical manufacturers and wholesalers are obliged to: "ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorized to supply medicinal products so that the needs of patients in the Member State in question are covered."[105]

3. Marketing Authorizations

In the past, companies wishing to launch a new medicine had to apply separately for an approval in each EU member state, which had different law standards on drugs. The single market approach for pharmaceuticals led the EU to establish two approval procedures in 1995. However, the approval alone is not enough in order to sell drugs in the majority of EU countries: almost all EU Member States use a strict price regulation on pharmaceuticals, forcing traders to carry out lengthy negotiations with health authorities. Additionally, some Member States determine that the starting price shall be at the average or even minimum price level compared to other countries.[106]

In order to get a marketing authorization, granted by the Member State or the European Medicines Agency (EMA, *formerly* EMEA), a pharmaceutical company has to show research results of the

---

[102] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 186 (2011), *Para. 1 of Art. 168 TFEU, reads as follows: "The Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."*

[103] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ 1989 No L40/8; 18.03.2013 the Commission has adopted the amended proposal for the above mentioned directive, COM/2013/166 final/2

[104] Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27, amending Directive 2001/83 on the Community code relating to medicinal products for human use, [2004] O.J. L136/34

[105] Art.81(2) of Directive 2001/83

[106] P.M. Danzon & A.J. Epstein, *Effects of Regulation on Drug Launch and Pricing in Interdependent Markets*, National Bureau of Economic Research Working Paper 14041, at 9-10, (2008)

safety, quality and effect of a medicinal product. The pharmaceutical company or other party launching the medicine may choose which of two procedures they prefer.

Encouragement of parallel trade in pharmaceuticals in the EU has sometimes accompanied the harmonization of the approvals. Thus, in *De Peijper*[107] in 1976, the ECJ stated that product testing which was performed in the Member State of origin should be accepted by the importing Member State. Thus, the imported product does not require new extensive tests guaranteeing the product's safety, quality and efficacy.[108]

Due to the fact that information protecting public health has become available to the controlling authorities in the Member State once the product was put on the market for the first time, a parallel imported product is subject to a simplified authorization process compared to the one needed for the original product provided, however, that the imported product has a marketing authorization in the Member State of origin. It also has to be substantially the same as the product which has been granted a marketing license in the destination country. The license for the parallel imported product remains valid even if the original manufacturer later cancels it in the destination country. According to the Commission, the parallel import license may be refuted only on the grounds of public health safeguarding.[109]

4. Price Regulation in Pharmaceuticals

EU Member States have the right to control their pharmaceutical expenses which form a big part of the health care budgets.[110] However, this shall not result in discrimination against parallel imported products. In general, the ECJ has applied Article 34 TFEU to pricing controls of medicine less strictly so far they do not cause barriers to trade. The party who invokes Article 34 TFEU shall show that price regulation constitutes discrimination against parallel imports, e.g. when the regulation does not allow including into price calculations costs, which have occurred outside the

[107] Judgment of 20 May 1976 *Case C-104/75 Adriaan de Peijper, managing Director of Centrafarm BV (De Peijper)* [1976] ECR 613.
[108] L. Hancher & W. Sauter: EU Competition and Internal Market Law in the Health Care Sector, 111 (2012)
[109] S. Valliluoto, Lääkehuollosta lääkemarkkinoihin – Arvoketju ja Sääntely, Kilpailuviraston Selvityksiä 2/12, at 57, *see also*, COM/2003/839final, Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted
[110] Article 168(7) TFEU

Member State. The same concerns price freezes and profit regulation which may infringe Article 34 TFEU in case importers are not allowed to recoup their costs.[111]

Thus, for example in cases *Commission v. Belgium* and *Commission v. Italy*[112] the Commission failed to prove that price and profit regulation of these two national regimes was discriminating against parallel imported products and thus the ECJ upheld the legality of the national regulations.

An imported product is not allowed to entry the market of a Member State which has not included it into the list for imbursement by its health care fund. In *Roussel* (1983) and *Duphar* (1984)[113] the ECJ took a balancing view on the interests of Member States trying to keep health costs at a reasonable level through price controls against the free movement right of pharmaceutical companies. In *Duphar* the ECJ concluded, based on objective criteria, that a national regime for controlling the costs was justified as pharmaceutical expenses were covered not by consumers but by the social security funds.[114]

The constant question in EU policy towards pharmaceutical sector is the market fragmentation, which basically derives from divergent national price and profit controls. The Commission and parallel traders have traditionally relied on the principles of free movement and undistorted competition, as correcting factors in removing obstacles to trade and competition. However, the type of intervention in question has not met the needs of this research-based industry. The presence of parallel imports and Commission's support to it is a persistent issue in the industry. The fragmentation of the market will continue as national governments are unwilling to give up the sovereignty on price and profit controls to European institutions. The harmonisation attempts of price controls have been abandoned following the adoption of the Price Transparency directive.[115]

---

[111] L. Hancher & W. Sauter: EU Competition and Internal Market Law in the Health Care Sector, 113 (2012)

[112] Case C-249/88 *Commission v. Belgium* [1991] ECR I-1275; Case 56/87 *Commission v. Italy* [1988] ECR 2919

[113] Judgment of the Court on 29 November 1983 in *Case 282/82 Roussel Laboratoria BV and others v. The Netherlands (Roussel)* [1983] ECR 3849; Judgment of the Court on 7 February 1984 in *Case* C-238/82, *Duphar BV and others v. The Netherlands* (Duphar) [1984] ECR 523

[114] L. Hancher & W. Sauter: EU Competition and Internal Market Law in the Health Care Sector, 113 (2012)

[115] L. Hancher, *The EU pharmaceuticals market: parameters and pathways in* Mossialos, E. (Ed.), Health Systems Governance in Europe: The Role of European Union Law and Policy, 635 at 637 (2010); see also Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ 1989 No L40/8

The harmonisation of price and profit controls is currently on a minimal level and the reform attempts of the Price Transparency directive have strongly been resisted. Instead, the EU has tried to solve the problems through political initiatives based on consultations and cooperation.[116]

The enlargement of the EU has brought more challenges, when the price differences have increased and national health budgets have still significant disparities. The development in case law shows that the traditional role of competition policy in the pharmaceutical sector might need re-assessment of competing targets of public health and pharmaceutical industry in order to ensure both affordability of drugs and incentives for innovation. This development will be discussed in more detail in chapter D, where case law regarding competition in pharmaceutical parallel trade will be examined.

III. Innovation in the Pharmaceutical Sector

This chapter examines the importance of innovation to pharmaceutical sector. Research and development is vital especially for the pharmaceutical sector as it brings new innovative drugs to the market. Parallel trade of pharmaceuticals is said to reduce the prices of drugs through its competitive effect. These two objectives can both be seen beneficial for consumers. However, there seems to be a tension between these objectives, which is much debated in the economic and legal literature. As long as parallel trade reduces the prices, it is beneficial for the consumers; however the decline in manufacturers' profits may lead to a reduction of research and development (R&D). Reduced innovation is one of the claims made by pharmaceutical manufacturers in competition law cases, these claims will be more analyzed in Chapter D.

R & D of pharmaceuticals takes significantly much time and money. It takes about 12 – 13 years to launch a medicine on the market after the active agent was developed, and the price of a new medicine has been estimated to be around €800 million. The views on the price of developing a medicine vary: manufacturing companies have presented the price to be about €800 – 1000 million euro, while in some connections the estimated price has been around 500 million euro, see In addition, medical research contains several risks; among 10 000 developed molecules only 1-2 end

[116] L. Hancher, *The EU pharmaceuticals market: parameters and pathways in* Mossialos, E. (Ed.), Health Systems Governance in Europe: The Role of European Union Law and Policy, 635 at 661 (2010)

up on the market as a new medicine. The researching pharmaceutical industry invests in R & D more than any other industry or institution. The investments of the researching pharmaceutical industry represent about 17 per cent of their total sales. In this context, the role of the patent system is to enable the pharmaceutical company to receive back the money invested in R & D.[117]

The pharmaceutical industry is an important sector in Europe in terms of production, revenue and employment. In 2008, it amounted to about 3.5% of the total manufacturing and 19.2% of the R&D expenditures in the EU, therefore it can be considered one of the most successful industries in Europe.[118] In 2008, the pharmaceutical industry provided 117,000 employment units in regard to R&D and invested €27,2 billion to R&D. European pharmaceutical sector is performing well and growing, but recently there have been indications that the competitiveness on the EU pharmaceutical market is not able to keep up with the development of the US industry, which is now leading in regard to the sales revenue put into R&D which invested about $38,4 billion in 2008.[119]

The recent figures, presented in 2013 by the European Federation of the Pharmaceutical Industries and Associations (EFPIA), show that between 1990 and 2012 R&D investment in the US grew 5.4 times, while in Europe only 3.8 times. In 2012 Europe invested €30,000 million in R&D whereas the investment in US was $36,810 million. However, the EU is not losing competition only to US in this regard, since the gradual migration of R&D investments to fast-growing market such as India, Brazil and China has taken place in recent years.[120]

According to the European Commission, while Europe was once known as "world's pharmacy", the number of new drugs originated in Europe has decreased drastically. Until 1998, seven out of ten new drugs originated in Europe, today only three out of ten are from Europe.[121] As a response to the decrease in European R&D the Commission and the pharmaceutical industry have started

---

[117] J.Joukas, Lääkevalmisteiden uudelleenpakkaaminen Euroopassa in K. Sorvari (Ed.), Teollisoikeudellisia kirjoituksia XI, 25 at 101 (2010)
[118] C. Desogus, Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade, 27-28 (2011)
[119] Ibid at 28
[120] Information reproduced online at http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf last visited on 28 April 2014
[121] The European Commission Press Release No. IP/08/662, 30 April 2008, "Public-Research Initiative to boost the competitiveness of Europe's pharmaceutical industry"

the implementation of the Innovative Medicines Initiative (IMI)[122]. One of the major challenges to answer with this initiative is the insufficient R&D investment in the pharmaceutical industry.

IV. Conclusions

The Community legislation provides that pharmaceutical producers and wholesalers ensure continued supplies to pharmacies and consumers of appropriate medicinal products. In order to secure that, the Commission has followed the potential anticompetitive behaviour of drug companies probably leading to increase of prices. At the same time, national health authorities have the right to control their medicine expenses by defining price levels. Member States allow only those medicines to enter their market which are in the list for reimbursement by the country's health care fund. National price and profit controls have claimed to be one of the main reasons why the European drug industry has been losing competition to the US and other fast-growing markets, especially in developing new drugs.

The EU and Member States regulate drug industry particularly through their secondary legislation. The launch of new drugs is controlled through special authorization procedures. However, the most important regulation related to the special status of the drug industry is the price regulation by the Member States which has partially resulted in market fragmentation as drug prices are not converged within the EU. Therefore the remaining price differentials are a prerequisite for parallel trade of medicines. The harmonization of prices through the modernization of the Price Transparency directive has been resisted and thus political consultations and cooperation have been suggested for resolving problems. Also parallel trade has been seen as a harmonisation tool due to its ability to decrease medicine prices in the countries where medicines are expensive.

The pharmaceutical sector is made special by innovation activities which are the basis of the whole research-based drug industry. The largest part of the producing process of the drugs is R&D which takes the major share of the drug industry's assets. Thus, drug manufacturers have referred in Competition law to these specific features, especially to pricing policies and innovation development. These factors will be discussed in the next chapters.

[122] Information available at http://www.imi.europa.eu/, (last visited on 13 April 2014)

D. Case Study: Dual Pricing and Refusal to Supply in the Pharmaceutical Sector

I. Introduction

As already mentioned in Chapter B, dual pricing arrangements and refusal to supply are means used by the drug manufacturers in order to block parallel imports. Issues related to dual pricing were discussed in case *GlaxoSmithKline v. Commission*[123]. Further, refusal to supply was covered in cases *Syfait*[124] and *Sot Lelos*[125]. The Court dismissed case *Syfait* for procedural reasons, but AG Jacobs gave his significant opinion in the matter, discussing particularly the special characteristics of the pharmaceutical industry and the impact of parallel imports. The Court gave its decision regarding the same matter in case *Sot Lelos.*

This Chapter analyzes the judgment of *GlaxoSmithKline* related to application of Article 101 TFEU, as well as cases *Syfait* and *Sot Lelos* relative to the application of Article 102 TFEU. The judgments are analyzed from the view of special characteristics of the drug industry.

II. Article 101 TFEU - GlaxoSmithKline v Commission

Facts of the Case

Glaxo Wellcome SA (GW), which is a subsidiary of GlaxoSmithKline Services Unlimited (GSK), proposed differentiated prices for 82 pharmaceuticals to its wholesalers in Spain. According to its sales conditions, GW sold reimbursable medicines to Spanish hospitals and pharmacies with lower prices and charged higher prices for products exported to other Member States (dual pricing

[123] Judgment of the Court on 6 October 2009 in *Joined Cases C-501/06; C-513/06; C-515/06 and C-519/06 GlaxoSmithKline Services Unlimited v. Commission* [2009] ECR 9291 (*Glaxo*)
[124] Judgment of the Court (Grand Chamber) of 31 May 2005 in *Case C-53/03 Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE* [2005] ECR I-4609 (*Syfait*)
[125] Judgment of the Court (Grand Chamber) of 16 September 2008 in *Joined cases C-468/06 to C-478/06 Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline AEVE Farmakeftikon Proïonton* [2008] ECR I-7139 (*Sot Lelos*)

system).[126] In the Commission's decision, GW had infringed Article 101(1) TFEU on the facts that it had with its wholesalers entered into an agreement according to which GW charged for reimbursable medicines meant to Spanish hospitals and pharmacies lower prices, while for products exported to other Member States prices were higher. GW's request for exemption of the agreement under Article 101(3) was rejected by the Commission.[127]

Court of First Instance in GSK

The Court of First instance ruled on the matter and stated that the objective of Article 101(1) TFEU, in particular for the mission of market integration, is to prevent companies, who aim at restricting competition, from reducing consumer welfare. The Court came to a conclusion that Article 101(1) is not applicable solely on the grounds that the agreement aims at partitioning of the common market and limiting of parallel trade in pharmaceuticals. In addition to the conclusion that the agreement has an obvious impact on trade within the EU, also an analysis is needed on whether this kind of agreement has as its object or effect the prevention, restriction or distortion of competition on the market so that it harms the end consumer. This kind of analysis must be supplemented if it is obvious that the conditions of the agreement are not altering competition.[128]

The CFI found, as the Commission earlier, that Glaxo's sales conditions were in breach of Article 101(1). However, it rejected the Commission's other finding that the object of the agreement was to restrict competition.[129] Consequently, while it has been ruled that an agreement which aims at limiting parallel trade must be interpreted to have as its object the prevention or restriction of competition, it applies only when the end consumer may be deprived by the agreement of mentioned advantages. Given the judicial and economic context, the CFI established that it could not be presumed that dual pricing conditions of the agreement would cause competition restraint leading to detriment of the end consumers of pharmaceuticals.[130] Considering the particular features of the pharmaceutical sector, the CFI stated that due to the regulation the prices of pharmaceuticals are to a large extent removed from the law of supply and demand and therefore it cannot be presumed that parallel trade reduces prices and increases the welfare of consumers.[131]

---

[126] *Joined Cases C-501/06; C-513/06; C-515/06 and C-519/06 Glaxo* v *Commission* [2009] ECR 9291
[127] *Ibid*
[128] Judgment of the Court of First Instance 27 September 2006 in *Case T-168/01, GlaxoSmithKline Services Unlimited v. Commission* [2006] ECR II-2969, paras 118-119
[129] A. Dostert, *Parallel Trade in Pharmaceutical Products Within the Internal Market: The Recent Glaxo Judgment of the E.C.J.*, 16 The Columbia Journal of European Law Online, 25 at 26 (2009)
[130] *Case T-168/01, Glaxo v. Commission*, [2006] ECR II 2969, paras 121-122
[131] *Ibid*, para 147

The Court then analyzed the possible anticompetitive effect of the agreement and concluded that the agreement had such effect, as it reduced consumer welfare by preventing the participation of Spanish wholesalers in the intra-brand competition in importing countries.[132]

The CFI considered the possibility of an exemption under Article 101(3) TFEU and stated that any agreement restricting competition might benefit from an exemption. In order to apply that provision, following conditions must be sufficiently satisfied. First, the agreement must enable to improve the manufacturing or distribution systems, or to promote economic or technological progress; second, a fair share of the benefits must be passed to the consumers; third, participating enterprises must not be addressed any dispensable restrictions; and fourth, the agreement must not give means for eliminating competition in relation to an essential part of the goods in question. Arguments and evidence must, however, be shown in order to demonstrate fulfilment of those conditions in accordance with Article 101(3).[133]

The CFI considered also the efficiency effects of parallel trade and its impact on innovation. It criticized the Commission of failing carrying out a proper examination and did not take into consideration all the evidence and factual arguments submitted by GSK. The Commission neither reasoned its conclusion when arguing that it was not proven: first, that parallel trade was capable to lead to a loss in efficiency by impairing GSK's capacity for innovation; second, and that sales conditions were capable of enabling a gain in efficiency to be achieved by improving innovation.[134] Moreover, the CFI noted that the observation of the evidence clearly reveals that in the pharmaceutical sector the effect of parallel trade is ambiguous, since the gain in efficiency in the intra-brand competition must be compared with the loss of efficiency in inter-brand competition.[135] Both the Commission and GlaxoSmithKline appealed the case to the ECJ.

[132] *Case T-168/01, Glaxo v. Commission*, [2006] ECR II 2969, para 190
[133] Ibid, paras 233-234
[134] Ibid, para 303
[135] Ibid, para 296

The Court of Justice in Glaxo

In its judgment of 6 October 2009, the ECJ rejected the approach of the CFI regarding Article 101(1) and clarified certain issues on the application of Article 101(3).[136] The ECJ has already held that agreements which aim at limiting or prohibiting parallel trade are in principle considered to prevent competition as their object.[137]

The ECJ came to a same conclusion as in *Sot Lelos* that an agreement aiming at limiting of parallel trade is regarded restrictive of competition by its object. It stated that "there is nothing in that provision to indicate that only those agreements which deprive consumers of certain advantages may have an anti-competitive object. Secondly, it must be borne in mind that the Court has held that, like other competition rules laid down in the Treaty, Article 81 EC aims to protect not only the interests of competitors or of consumers, but also the structure of the market and, in so doing, competition as such. Consequently, for a finding that an agreement has an anti-competitive object, it is not necessary that final consumers be deprived of the advantages of effective competition in terms of supply or price". Therefore the CFI committed an error of law when it stated that the agreement would only restrict competition, if its object or effect was shown to be restrictive of competition as harming consumers.[138]

As regards the possible exemption under Article 101(3), the Court noted that in order to an agreement being exempted under Article 101(3), it must contribute to improve the production or distribution of goods or promote technical or economic progress. Those advantages must outweigh the possibly resulting disadvantages for competition.[139]

In its judgment, the ECJ clarified that the Commission had failed to take into account the specific features of the pharmaceutical sector in assessing the GSK's request for exemption. The Court noted that the specific features of the pharmaceutical sector may be considered under Article

---

[136] A. Dostert, *Parallel Trade in Pharmaceutical Products Within the Internal Market: The Recent Glaxo Judgment of the E.C.J.,* 16 The Columbia Journal of European Law Online, 25 at 257 (2009)

[137] *See to that effect, Case 19/77 Miller International Schallplaten v. Commission [1978] ECR 131, paragraphs 7 and 18, and Joined Cases 32/78, 36/78 to 82/78 BMW Belgium and Others v. Commission [1979] ECR 2435, paragraphs 20 to 28 and 31; Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P GlaxoSmithKline, para 59*

[138] *Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P Glaxo v. Commission*, [2009] ECR 9291, paras 63-64

[139] *Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P Glaxo v. Commission*, [2009] ECR 9291, para 92, *see to that effect, Consten & Grundig v. Commission*

101(3), when assessing the advantages and disadvantages of the agreement. Thus the ECJ recognized that no reasons *a priori* prevented Glaxo's agreement to be qualified for an exemption under Article 101(3).[140]

III. Article 102 TFEU – Syfait and Sot Lelos

1. C-53/03 Syfait v GlaxoSmithKline

Facts of the Case

GlaxoSmithKline (GSK) was distributing three pharmaceuticals (Lamictal for epilepsy, Imigran for migraine and Serevent for asthma) in Greece, from where some of GSK's wholesalers were supplying other Member States, especially the UK and Germany. In 2000, when there was a shortage of these three products, GSK stopped fulfilling the orders of its wholesalers and delivered drugs to hospitals and pharmacies through the firm Farmacenter AE. GSK restored its supplies to the wholesalers very soon but with limited amounts. Based on their inability to export medicines as much as earlier, the wholesalers took two complaints against GSK.[141]

They complained to the Greek Competition Commission that GSK refused to fulfil their orders. The Greek Commission referred to the ECJ in order to get clarification as to whether (and under which circumstances) a dominant pharmaceutical enterprise may refuse to fulfil the orders so that parallel trade is limited. However, the ECJ refused to rule because it was not competent under Article 234 of the EC Treaty, as the Greek Competition Commission did not represent 'a court or tribunal of a Member State' as required in the Article.[142]

---

[140] *Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P Glaxo v. Commission*, [2009] ECR 9291, paras 103-104

[141] A. Montesa Lloreda *in* Kanninen, Korjus & Rosas (Eds.), EU Competition Law in Context at 251 (2009)

[142] Turner-Kerr, Peter, *Finally a bit of clarity for pharmaceutical companies; but uncertainties remain: judgment of the ECJ in Sot Lelos kai Sia EE v GlaxoSmithKline AEVE*, European Competition Law Review, 30(2), at 57 (2009)

Opinion of AG Jacobs

Despite of the decision of the ECJ, Advocate General Jacobs gave his opinion on the matter. AG Jacobs considered whether GlaxoSmithKline's activities could be objectively justified with reference to the specific characteristics of the pharmaceutical industry and the economic impact of parallel imports.

AG Jacobs came to the conclusion that restricting the supply of pharmaceuticals GlaxoSmithKline did not necessarily abuse its dominant position, even though the intention was to limit parallel trade. Though this kind of conduct is normally considered restrictive, taking into account the specifics of the pharmaceutical market, the actions could be objectively justified.[143] AG Jacobs reasoned his decision on three grounds.

Firstly, based on previous case law, the dominant undertaking has an obligation to supply only occasionally, for example when the interruption of supply would seriously harm competition in the downstream market[144] between the undertaking and its customer or in the supply market between the undertaking and its competitors (actual or potential).[145]

Secondly, referring to *United Brands,* obligation to supply is only limited to the ordinary orders and the undertaking could defend its commercial interests. Furthermore, the Court has limited the obligation to supply to dominant undertakings and with the possibility of objective justification.[146]

Thirdly, referring to the Commission decision in *Microsoft* and *Verizon* case in United States, when demonstrating the abusiveness of the refusal to supply, account should be taken the specific economic and regulatory context of the pharmaceutical industry.[147]

In the question whether the GlaxoSmithKline's refusal to supply would be objectively justifiable, AG Jacobs lists three factors to take into account: first, the pervasive regulation of price and distribution in the European pharmaceutical market; second, the possible impact of uncontrolled

[143] Opinion of AG Jacobs in *Case C-53/03 Syfait*, [2006] ECR II-2969, paras 69-70
[144] ie. next stage of the production or distribution chain
[145] Opinion of AG Jacobs in *Case C-53/03 Syfait*, [2006] ECR II-2969, para 66
[146] ibid, para 67
[147] ibid, para 68

parallel trade on pharmaceutical undertakings as regards to the economics of the market; and third, the effect of parallel trade upon consumers and purchasers of pharmaceuticals.

According to AG Jacobs, the pervasive regulation in the pharmaceutical sector at national and Community level distinguishing it from other sectors should not be ignored. Member States intervene to limit the payable prices of pharmaceuticals, therefore prices vary between the Member States which makes the opportunities to parallel trade. Pharmaceutical manufacturers have a duty to guarantee the availability of the pharmaceuticals[148], which proves the fact that normal conditions of competition do not apply for this sector. The legal and moral obligations placed on pharmaceutical manufacturers makes it questionable, whether it is reasonable to require manufacturers to supply wholesalers engaged in parallel trade in low-priced Member States.[149]

Considering the economic factors, the high level of innovation in this industry should be taken into consideration. Due to the high fixed costs of R&D in the manufacturing process of pharmaceuticals, the decision to develop a new product depends solely upon whether the manufacturers gain sufficient profits to recoup the investments to R&D. Therefore manufacturers prefer to supply markets where the price is above the variable cost. Prohibiting restrictions to supply creates a threat that manufacturers will delay the launch of new products in certain markets to avoid supplying parallel traders. This would lead to even greater fragmentation of the market.[150]

Furthermore, AG Jacobs considers the effect of parallel trade upon consumers and purchasers in Member States. In several Member States, the largest contribution towards the price of pharmaceuticals falls to the social health insurance, therefore there are no the benefits to the actual consumers. Moreover, parallel trade does not always benefit even the public bodies purchasing the drugs, since the benefits of price differentials created by parallel trade are being completely absorbed as profit to parallel traders.[151]

2. Joined Cases C-468/06 – C-478/06 Sot Lélos kai sia v GlaxoSmithKline

[148] Article 81 of Directive 2001/83
[149] Opinion of AG Jacobs in Case C-53/03 Syfait, [2006] ECR II-2969, paras 77-88
[150] Ibid, paras 89-95
[151] Ibid, paras 96-99

Another complaint was brought before the Greek Courts by the applicants on GSK's behaviour as an abuse of a dominant position. The Greek Court of Appeal, in turn, referred to the ECJ several questions similar to the ones asked by the Greek Competition Commission earlier.[152]

First in substance, the Greek Court of Appeal asked whether a dominant company's refusal to fulfil orders received from its dealers in order to limit parallel trade is an abuse of Article 102 TFEU, especially if such business is profitable based on price differentials caused by interference of Member States. It also asked the ECJ to answer when such refusal would mean an abuse in case the first answer was negative.[153]

Sot Lélos clarified the application of Article 102 TFEU in the situation where a dominant company had reduced supplies to its wholesalers with the aim at restricting of parallel imports.[154]

Opinion of AG Ruiz-Jarabo Colomer in Sot Lélos

Referring to *Commercial Solvents* and *United Brands*, AG Colomer stated that a dominant undertaking avoiding supply of goods in a situation where there are no substitutes, reserving the export market to itself, commits an abuse under Article 101 TFEU.[155] However, in regard to the objective justification of such action, he states that the undertaking could possibly justify its actions when it could prove one of the following: first, that matters of market regulation such as setting of prices would force it to refuse supplying wholesalers; second, that the sole motivation was to protect its legitimate interests excluding in this case, the impact of incentives to innovate; or third, the economic benefits of the conduct. Also the conduct must be shown as unavoidable and appropriate (proportionality test).[156]

---

[152] Turner-Kerr, Peter, *Finally a bit of clarity for pharmaceutical companies; but uncertainties remain: judgment of the ECJ in Sot Lelos kai Sia EE v GlaxoSmithKline AEVE*, European Competition Law Review, 30(2), at 57 (2009)
[153] A. Montesa Lloreda *in* H.Kanninen, N.Korjus & A.Rosas (Ed.), EU Competition Law in Context, at 252 (2009)
[154] T. Graf & S. Hallouet, *Dominant companies may not refuse ordinary orders with the aim of restricting parallel trade: the ECJ judgment in GlaxoSmithKline AEVE,* European Competition Law Review, 30(4), 194 at 194 (2009)
[155] Advocate General Ruiz-Jarabo Colomer in Joined Cases C-468/06 – C-478/06, *Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline* [2008] ECR I-7139, para 46
[156] Ibid, paras 121-122

AG Ruiz-Jarabo Colomer admitted that because of the price regulation, the pharmaceutical market cannot be considered to operate under normal competitive conditions. However, he stated that manufacturers have some kind of influence on the price negotiations and therefore have a degree of strength in the market.[157] Furthermore, AG Ruiz-Jarabo Colomer rejected GSK's argument that the duty to supply in Greece prevents it from meeting orders from the wholesalers.[158]

Concluding, AG Ruiz-Jarabo Colomer had an opinion that GSK could not prove any possible justifications in this case.

The Court of Justice in Sot Lelos

In its judgment, the Court of Justice states that the established case-law shows that the refusal of a dominant undertaking to supply, is liable to eliminate competition in that market.[159] The Court then considered whether the conduct was abusive.

First, the Court assessed the GSK's argument that parallel trade does not necessarily bring benefits to the final consumer. The Court noted that the assessment should not be based on the fact how much parallel trade benefits the final consumer. Though, the Court agreed that the benefits to consumers might be lower than benefits to wholesalers engaged in parallel trade. Regardless, the Court was on the opinion that parallel trade is capable of exerting pressure on prices and therefore creates financial benefits to social health insurance funds and patients.[160]

Next, the Court examined the impact of State regulation of prices on the pharmaceutical market. In accordance of the view of AG Ruiz-Jarabo Colomer, the State regulation of pharmaceutical prices and reimbursement does not entirely remove the prices from the law of supply and demand and that manufacturers can to some point affect the pricing of those products. Furthermore, until the expiry of the patent, price competition between a manufacturer and a parallel trader is the only possible form of competition. Therefore, for the practices of a dominant company aiming at

---

[157] Advocate General Ruiz-Jarabo Colomer in *Joined Cases C-468/06 - C-478/06 Sot Lelos,* [2008] ECR I-7139, para 93
[158] Ibid, paras 94-97
[159] *Joined Cases C-486/06 – C-478/06 Sot Lelos*, [2008] ECR I-7139, para 34
[160] Ibid, paras 53-57

avoiding of parallel trade, can be no escape from the prohibition of Article 102 TFEU since these practices partition national markets and neutralize the benefits of effective competition.[161]

The Court also rejected the argument of GSK that parallel trade might affect the future marketing of pharmaceuticals in certain low-priced countries. It noted that Community competition rules cannot be interpreted in such a way that the only choice left for the manufacturers would be not to place its products on the market at all.[162]

The Court did not examine the GSK's claim of the reduction of investments due to parallel trade, but it stated that it would be permissible for the undertaking to take reasonable and proportionate actions to protect its legitimate interests against parallel traders. It is therefore necessary to assess whether the orders from the wholesalers are out of the ordinary.[163] The Court left the proportionality test to the referring court, to ascertain whether the orders were ordinary in the light of previous business relations between the manufacturer and the wholesaler engaged in parallel trade.[164]

IV. Conclusions

Pharmaceutical companies consider that specific factors of the sector, such as obligation to supply, R&D spending, and price interference by Member States shall be analyzed under Competition law, and refer to these factors in cases brought against them. Thus, GlaxoSmithKline referred to these arguments in *Syfait* and had acceptance for its arguments from AG Jacobs in 2004, but no judgment was given. According to AG Jacobs, the special features of the pharmaceutical sector would justify a restriction, when it is considered reasonable and proportionate. AG Jacobs was willing to give some kind of special position to the pharmaceutical industry. However, this view was rejected by the ECJ in *Sot Lelos*.

In ECJ's decision in *Sot Lelos*, refusal to supply existing customers with ordinary orders was considered to be against Article 102 TFEU. The manufacturer is obliged to supply, unless an existing customer is requesting amounts out of the ordinary. Though, the Court did not answer,

---

[161] *Joined Cases C-486/06 – C-478/06 Sot Lelos*, [2008] ECR I-7139, paras 58-66
[162] Ibid, para 68
[163] Ibid, paras 70-71
[164] Ibid, paras 73

how the ordinary orders are described. However, means for protecting commercial interests (company's profits) would be allowed to a reasonable and proportionate extent, provided they do not aim at reinforcing dominance. The ECJ rejected the argumentation of efficiency defences, such as the impact of parallel trade on end consumers or R&D arguments. This case benefitted both manufacturers and parallel traders: while the restriction was not capable of escaping the application of Article 102 TFEU, the ECJ still recognised a possibility of an undertaking to protect its commercial interests.

Regarding dual pricing in *Glaxo*, the Commission made a traditional decision, stating that restrictions of parallel trade constitute a restriction of competition by object. That was though challenged by the CFI which established that pharmaceutical sector differs from others and thus there was no restriction of competition by object under Article 101(1). However, the CFI found in this case a restriction by effect. It also criticized the Commission for the refusal of an exemption under Article 101(3) TFEU.

The ECJ established in *Glaxo* that agreements which aim at limiting or prohibiting parallel trade constitute prevention of competition by object, and this principle covers also the pharmaceutical sector. Furthermore, the Court held that not only those agreements depriving consumers of advantages of competition, e.g. lower prices, are considered to have anti-competitive object under Article 101(1), but also competition as such and the market structure are protected by Article 101 TFEU.

The ECJ was not willing to give the pharmaceutical sector any kind of immunity from the Competition rules in *Glaxo* or in *Sot Lelos*. However, in *Glaxo*, the Court recognized that the specific features of the market and the efficiency claims should have been assessed in relation to the requested exemption under Article 101(3). The issue of claims on the negative effect of parallel trade on R&D investment though seems to remain open, but in general the outcome of the judgments is that pharmaceutical industry is paralleled by any other sector and thus its 'specificity' under Competition law is rejected.

E. The Economic Effects of Parallel Trade

I. Introduction

The Commission and the EU Courts have supported parallel trade, since it forms an essential part of free movement with its aim to create competition in prices, to the benefit of the consumers. However, it is not clear whether the reduction of prices ultimately leads to consumer benefit.

According to EU competition law, the consumer's benefit is the prerequisite for acceptability of parallel trade activities. Thus, agreements restricting competition would be admissible under Article 101(3) TFEU based on the evidence that the advantage for consumers is larger than the adequate disadvantage.[165]

In *Syfait*, Advocate General Jacobs analyzed the special nature of the pharmaceutical sector and came to the conclusion that refusal to supply would be capable of objective justification. When estimating the possible justification, the pervasive price regulation of the pharmaceutical market, the economic effects of parallel trade to innovation and its benefits to consumers must be taken into account.

However, in *Sot Lelos*, the ECJ did not give the pharmaceutical industry any special position despite of the characteristics. However, the Court has indicated that a pharmaceutical company could take reasonable and proportionate steps to protect its commercial interests.

In *Glaxo*, the ECJ agreed with GSK that the benefits to parallel traders might be higher than the benefits to consumers. However, the Court emphasized the fact that parallel trade is capable of exerting pressure on prices, though the consumers benefit from lower prices. The Court examined the impact on prices and agreed with AG Ruiz- Jarabo Colomer that the regulation does not remove the prices entirely from the law of supply and demand since the manufacturers have some kind of influence on prices. Therefore parallel trade would be the only form of competition until the patent expires.

[165] M. Alkio and C. Wik, Kilpailuoikeus, 141 (2009)

There are many different views on who really benefits from parallel trade and how large are the savings to the patients and health care providers. This is one of the factors why the economic effects have not been taken into consideration in the pharmaceutical cases on a larger scale. This Chapter will analyze the effects of parallel trade on the pharmaceutical sector and compare the findings to the statements of the EU Courts in cases assessed in Chapter D. The Chapter will first discuss the impact of parallel imports on the prices of pharmaceuticals, followed by the analysis of its resulting effects to research and development.

II. The Effects to Prices of Pharmaceuticals

A logical, expected consequence of parallel trade in pharmaceuticals would be that medicine prices decrease as parallel trade boosts competition.[166] According to some theories, consumers would ultimately profit from competition between companies because these companies will constantly develop new products and produce goods demanded by consumers. Also, they are not able to keep high prices artificially.[167] But whether parallel trade benefits consumer welfare, is not self-evident. Instead, some studies suggest that parallel trade does not create welfare benefits. The high level of regulation in national markets might affect the theory of price reduction in the importing countries. The results of the studies conducted are not unanimous.[168]

Ganslandt and Maskus studied the impact of parallel imports of medicines on prices on the Swedish market. During the examination period, the prices of pharmaceuticals increased on average by 6,64%, whereas the prices of parallel imported medicines grew only by 2,88%. Furthermore, if the medicinal product was under parallel imports, the medicine prices of the original producer grew on average by 6,38%, i.e. slightly less than the average of all pharmaceuticals. Also, the price differential indicates statistical significance. The more there were parallel traders importing a medicine; the lower sank the price of the original manufacturer. This would show that parallel imports limit also original producer's pricing policy. [169] In another study the same authors stated that if enterprises are forced along with parallel imports to a uniform

[166] G. Tsouloufas, *Limiting pharmaceutical parallel trade in the European Union: regulatory and economic justifications.* European Law Review, 36(3), 385 at 392 (2011)
[167] C. Waelde, Contemporary Intellectual Property Law and Policy, page 869 (2014)
[168] G. Tsouloufas, *Limiting pharmaceutical parallel trade in the European Union: regulatory and economic justifications.* European Law Review, 36(3), 385 at 392 (2011)
[169] M. Ganslandt and K.E. Maskus, "Parallel imports and the pricing of pharmaceutical products: evidence from the European Union", *Journal of Health Economics,* 1047 at 1047-1051 (2004)

wholesale pricing across the markets, also retail prices in the whole market region will become equal. Thus, in that case retail prices are on average higher, which leads to decreased consumer welfare.[170]

According to a Danish study, in two of the studied Member States, Germany and Denmark, was found clear evidence of price reduction after parallel imports started. The fact that prices did not lower in Sweden, was explained by the changes of regulation, and the Clawback system[171]complicated the evaluation in the UK.[172] Concluding, the study found that parallel trade created considerable direct savings to consumers and to public health care expenditures.[173]

The study by York Health Economics Consortium had similar findings where it concluded that parallel trade of pharmaceuticals resulted in savings for the consumers, pharmacists and health care systems.[174]

The results differ in the study of London School of Economics. In the study countries, price differentials do not benefit the patients almost at all. Instead the benefit remains largely at insurance companies and public health care organizations, who carry the most part of the medicine costs. For example in Great Britain, parallel imported product is for the end user and doctors identical with the product imported by the original producer, including the price, because of the reimbursement system. Thus, real competitive pressure is not created.[175] Also, this research denied the hypothesis that parallel imports of medicines from low-price Member States to high-price Member States lead to price competition and decreases prices in the importing countries.[176] In

---

[170] M. Ganslandt and K.E. Maskus: Wholesale Price Discrimination and Parallel Imports, CESifo Working Paper No. 1951, at 35-36 (2007)

[171] In the Clawback system the state reduces the imbursement received by the pharmacy in regard to parallel imported drugs sold by the pharmacy.

[172] U. Enemark, K. Moeller Pedersen & J. Soerensen, The economic impact of parallel import of pharmaceuticals. University of Southern Denmark Centre for Applied Health Services Research and Technology Assessment, 49 (2006)

[173] Ibid at 66-69

[174] West, Peter, Mahon, James: Benefits to Payers and Patients From Parallel Trade, York Health Economics Consortium, May 2003, 67

[175] Kanavos et al. *The economic impact of pharmaceutical parallel trade in European Union Member States: a stakeholder analysis,*135 (2004), note also that in Clawback system the state reduces the imbursement received by the pharmacy in regard to parallel imported drugs sold by the pharmacy.

[176] G. Tsouloufas, *Limiting pharmaceutical parallel trade in the European Union: regulatory and economic justifications.* European Law Review, 36(3), 385 at 392-393 (2011); *see also,* Kanavos et al.,*The economic impact of pharmaceutical parallel trade in European Union Member States: a stakeholder analysis,* 132-138 (2004)

these circumstances, the benefit created by potential price differentials, profits the health care system.

As a conclusion, there is no unambiguous answer to the question whether parallel imports reduce medicine expenses in the Member States. Also, it is not clear whether parallel trade promotes price competition and price reduction of pharmaceuticals caused by this competition. Furthermore, it is unclear which interest groups gain most from the parallel imports. In fact, there have been claims that the only group gaining from the parallel trade is parallel traders themselves. According to Kanavos and Costa-Font, 85% of the achieved profit goes to parallel traders, 13,2% to the health insurance system and 1% to the pharmacies.[177]

III. The Effects to R&D

According to the studies above, parallel trade in pharmaceuticals might bring consumer benefits by lowering prices in the importing countries. However, the loss of pharmaceutical manufacturers might result in reduction of innovation. According to Coscelli *et alia*, the level of investments in R&D depends on current and estimated producer profits. Thus, as parallel trade reduces drug companies' profits, it will likely result in less R&D investment. As demand for prescription drugs is inelastic while parallel trade is pure arbitrage which in practice does not add any value into the delivery chain, the manufacturers suffer from losses equal to the total benefits to consumers and delivery chain (consisting of parallel importers, wholesalers and pharmacists). Thus, the losses to pharmaceutical companies always exceed the profit gained by consumers through lower prices.[178]

According to the study of Kanavos *et alia*, the total benefit from parallel imports to the parallel traders is up to €704 million. The loss of surplus by the manufacturers is €755 million, of which the margin gained by the parallel importers is 93% after their supply costs. Consequently, it can be noted that parallel importers either use the price differentials mostly for covering of their activities or they keep the return by themselves.[179]

---

[177] P. Kanavos, and J. Costa-i-Font, *Pharmaceutical parallel trade in Europe: stakeholder and competition effects*. Economic Policy, 751 at 774 (2005)
[178] Andrea Coscelli, Geoff Edwards, Alan Overd, *Parallel trade in pharmaceuticals: more harm than good?* European Competition Law Review E.C.L.R. 2008, 29(8), 490 at 491
[179] Kanavos et al., *The economic impact of pharmaceutical parallel trade in European Union Member States: a stakeholder analysis,*127 (2004)

In Syfait, AG Jacobs stressed that the economic aspects of parallel trade must be taken into consideration when assessing objective justification of refusal to supply. According to Jacobs, innovation is an important factor of competition in the pharmaceutical industry and R&D of a new medicine usually requires notable investments. Furthermore, the decision to invest in a new medicine is depending for example on the manufacturer's expectations on the profits to cover R&D costs. If the price of a drug in one country will be generalised to a same level in the whole EU as a result of parallel imports, the researching pharmaceutical industry may not necessarily be able to cover all costs related to innovation activities. Thus, companies of research-based pharmaceutical industry would clearly have an incentive not to market their products in low-price countries, which would lead to delays of market launch of new products in those countries. According to Jacobs, this would result in reduction of production amounts of certain pharmaceuticals and worsening of welfare of consumers in the EU.[180]

In line with AG Jacobs were also Coscelli *et alia,* noting that parallel trade may harm consumers in exporting countries through delays in supplies of new drugs in situations where manufacturers are unwilling to put drugs on the low-price markets, preferring supplies into countries with higher prices. Instability in the delivery chain arise when parallel exporters divert supplies, meant for local consumption, to countries with higher prices. This effect strengthens the conclusion that restrictions would probably improve consumer welfare.[181] A recent study proves that parallel trade in the EU can lead only to upward price equalization. Therefore, static welfare effects of parallel imports seem to be neutral, at the most.[182]

IV. Conclusions

When evaluating total impact of parallel import, the long-term effects come up. Although it may generate short-term economic benefits, these benefits shall be proportioned with damage to other

[180] AG Jacobs in *C-53/03 Syfait* [2005] ECR I-4906, paras 89-95
[181] Andrea Coscelli, Geoff Edwards, Alan Overd, *Parallel trade in pharmaceuticals: more harm than good?* European Competition Law Review E.C.L.R. 2008, 29(8), 490 at 492
[182] G. Tsouloufas, *Limiting pharmaceutical parallel trade in the European Union: regulatory and economic justifications.* European Law Review, 36(3), 385 at 393 (2011); *see also:* P. Kanavos and S. Vandoros, *"Competition in prescription drug markets: is parallel trade the answer?"* Managerial and Decision Economics, vol. 31(5), 325 at 325, 336 (2010)

affected parties and with long-term, partially unforeseeable economic consequences. Some studies suggest that parallel trade is capable of generating only moderate savings to health care systems, while the negative impact in the form of medicine shortages in exporting countries as well as profitable counterfeiting are increasing. The main beneficiaries seem to be parallel distributors, whereas long-term price competition or benefits to end consumers seem not to come true which makes parallel trade an inefficient way of cost savings.

Empirical investigations regarding parallel trade's effect on R&D are lacking, but there are theoretical studies emphasizing that positive welfare effects of parallel imports may lose their relevance due to reduced innovation willingness.

The effects of parallel trade on consumer welfare are various. Consumers can buy medicines at a lower price provided than price differences are passed on to the prices paid by the patients. On the other hand, due to reduced incentives manufacturers may not be able to invest in R&D as much as earlier which might result in less new drugs in a long term. Moreover, consumers may be affected by higher prices or delays of new medicines and supply uncertainty in exporting countries. Thus, all above mentioned factors shall be taken into consideration when exemption under Article 101(3) is assessed in order to find out the net effect of parallel trade on consumer welfare.

Regarding the economic impact of parallel imports, AG Jacobs noted in *Syfait* that, due to the specific nature of the pharmaceutical sector, parallel import does not necessarily lower the prices for consumers as the end users in Member States usually pay only a small fixed share of the prescription medicine while the social insurance covers the remaining part. Nor do the public bodies or taxpayers benefit from parallel trade as the profits stay mainly at the distribution chain. The ECJ handled the same questions in *Lélos* and stated that price differentials in exporting and importing Member States do not necessarily mean consumer benefits in the from the parallel imports and instead parallel traders seem to benefit often most. Nevertheless, parallel imports may put pressure on prices resulting in benefits both for health insurance systems and patients.

F. Comparative Research

I. Introduction

Lowering the costs of prescription pharmaceuticals is a relevant issue both in Europe and in the US not least due to the fact that people live longer resulting in more health expenses at personal and governmental level. The attempts to reduce these expenses in the EU, e.g. through legalized parallel importation have been thoroughly discussed in earlier Chapters. The US and the European Union are the two main research-based pharmaceutical sectors and thus a business opportunity to parallel trade. However, possibilities for parallel traders to act in these markets differ – the US being more oriented on protection of R&D investments, while the EU encourages to competition by all means, including parallel trade in pharmaceuticals. This Chapter gives first an overview on the US legislation and case law regarding parallel trade and the exhaustion principle of IPR and then moves to the comparison of the current status of parallel trade in pharmaceuticals in these two markets.

As discussed earlier, the EU follows the principle of regional exhaustion where IPRs are exhausted when goods are put into circulation within the EEA. Free movement of goods and common market integration are prioritized over IPRs in the EU competition policy.

The United States applies the regime of international exhaustion to trade marks with a "common-control exception", where parallel imports may be blocked except if the trade mark owner and the parallel trader are in a parent-subsidiary relationship. Furthermore, the trade mark owner has to prove the different quality among products which could lead to confusion by consumers. In regard to patents and copyrights, the US applies national exhaustion, where the owners can prevent parallel trade relying on the specific right of importation. The background of this treatment is the thought that the monopoly rights ensure the recoup of the costs put on investments.[183]

In general, exhaustion is not agreed in any international agreements, due to differences in the interests of countries. The negotiations on TRIPS agreement did not achieve a global mutual understanding. Article 6 of the TRIPS agreement states: "For the purposes of dispute settlement

[183] K. Maskus, The curious economics of parallel imports, WIPO Journal, at 124 (2010)

under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." It does not take any position on exhaustion, instead leaves the rules on exhaustion for each country to decide.[184]

According to some opinions, "[t]he U.S.' bargaining position, supported by the pharmaceutical industry, has been that every nation should follow a rule of national exhaustion."[185] The Patent Law Act, Section 271, states that "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent." In general, court decisions in the US have confirmed that the patent owners are eligible to restrict parallel imports or reselling of their products, but there are though exceptions. In *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp.*[186] the patent owner was not entitled to block parallel imports as he had not unambiguously forbidden its licensee to resell the goods in the U.S. In *Jazz Photo v. International Trade Commission*[187] stated that"[t]o invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent." Thus, US patent owners could claim breach of their rights with regard to parallel imports of goods legally purchased outside the US.[188]

II. Different Approaches on Parallel Trade of Pharmaceuticals – The Comparison of EU and US

The EU Commission's and the US government's views on the approach to parallel trade are vitally different due to divergent exhaustion regimes of IPRs and priorities towards R&D of the pharmaceutical companies.

The EU legislation aims at harmonization of laws and creation of a common market in order to be a competitive player on the global market. More than protecting IPRs, the EU emphasizes harmonization of community laws and creation of a single market. The negative effects of parallel

---

[184] K. Maskus, The curious economics of parallel imports, WIPO Journal, at 124 (2010)
[185] R. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 Ford. L. Rev. 477 (2003).
[186] Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp., 266 F. 71 (2d Cir. 1920).
[187] Jazz Camera Photo v. Int'l Trade Comm'n, 264 F.3d 1094 (Fed. Cir. 2001)
[188] Kyle, Margaret, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in,* B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 339 at 344 (2009)

imports are outweighed by the single market goal. Furthermore, in the EU countries the governments pay for most of the expenses related to medicinal needs of the people and that is why they are interested in cheaper drugs offered by parallel traders.

In contrast, patent owners in the US are entitled to exclude others from using, importing or selling an invention under patent based on the priority focus of the lawmaker that R&D of new drugs must be secured.[189] This shows the clear difference compared to the EU strategy.

When discussing the differences in the US and EU, and possible implementation of the similar to the EU's parallel trade strategy in the US, it is vital to consider simultaneous fulfilling of the following conditions. First, patients have to seek for cheaper drugs; second, pharmacies must regularly offer parallel imported drugs; third, price differences between locally sourced and parallel imported pharmaceuticals have to be meaningful for payers (both for patients and social funds); fourth, continuous availability of drugs has to be secured; and fifth, patients should be able to rely on the quality and information about the drugs. Importation from countries with strong regulatory systems of pharmaceuticals is usually safe for consumers. Generally, the patients' situation regarding reimbursement of drugs is quite different in the US, where some patients pay all of their costs of prescription medicines, and many a significant share of their costs.[190]

Legalization of parallel importation may indeed decrease costs of prescription drugs for individuals. However, it does not necessarily by itself mean that drug prices become affordable to US consumers or reduce the costs of third-party payers, usually social insurance funds. In order to rationalize drug costs in the long run, a more cost-effective method than parallel importation could be intensified research on alternative medical treatments. [191]

In general, parallel trade in pharmaceuticals in not permitted in the US, but in regard to international versus national exhaustion of IPRs there are no specific court rulings available.[192] Thus, the US courts continue supporting patent proprietors to block parallel trade in

---

[189] J. A. Moore, *Parallel Trade, Unparallel Laws: An Examinations of the Pharmaceutical Parallel Trade Laws of the United States, the European Union and the World Trade Organization,* Richmond Journal of Global Law and Business, 77 at 83-84 (Summer 2006)

[190] P. Kanavos, D. Gross & D. Taylor, *Parallel Trading in Medicines: Europe's Experience and Its Implications for Commercial Drug Importation in the United States,* 28 (2005)

[191]Ibid at 29

[192] Kyle, Margaret, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in,* B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 339 at 348 (2009)

pharmaceuticals. The United States is a spokesman for free market, except of pharmaceutical industries, where the protection of patent holders is preferred over competitive markets. The US government is a close partner of drug companies. For example, it has used threats of trade sanctions in order to reduce illegal generic productions in several countries.[193] In addition, the US has made a preferential trading arrangement with several Central American and other states in order to restrict parallel imports of pharmaceuticals.[194]

While parallel importation (or re-importation) of pharmaceuticals is not legalized in the US, it occurs outside the authorized distribution channels and not much about its volume is known. However, the US Department of Health and Human Services estimated in 2003 that importation of drugs by individuals and through internet pharmacies was $695 million.[195] Thus, it is a remarkable form of unauthorized trade.

When trying to find reasons for an interest in parallel trade, the elasticity of demand shall be determined. More that patients' income matters the ability to substitute medicines. Usually, branded pharmaceuticals do not have perfect substitutes if adequate generic drugs are not available, but fairly close substitutes might be found. For example, there are on the US market several 'statins' including Pfizer's Lipitor blockbuster, and other 'statins' with similar indications; their effectiveness only may vary by individual.[196]

Price discrimination in relation to patients is legislated in the US drug market. It means that manufacturers are obliged to supply Medicaid at a price offered to any buyer of the drug and other agencies obtain special discounts. The relative pricing rule of the US government thus pushes other patients' private costs up. This extensive system has led to a situation where the same drugs under patent are sold at rather different prices.[197]

---

[193] J. A. Moore, *Parallel Trade, Unparallel Laws: An Examinations of the Pharmaceutical Parallel Trade Laws of the United States, the European Union and the World Trade Organization,* Richmond Journal of Global Law and Business, 77 at 85-86

[194] K. Maskus, The curious economics of parallel imports, WIPO Journal, at 125 (2010)

[195] A. Hollist & P. Ibbott, *How Parallel Trade Affects Drug Policies and Prices in Canada and the United States,* American Journal of Law & Medicine (32),193 at 194 (2006)

[196] Ibid, 193 at 199

[197] Ibid, 193 at 201

Parallel importation of pharmaceuticals is regulated in the Federal Food, Drug and Cosmetic Act (FDA)[198] and its amendments. Primarily, the Act is concerning safety issues and less exhaustion questions, but some provisions are still relevant to the importation of medicinal products. Only the US manufacturer of a pharmaceutical has the right to import that product into the US.[199] In order to import foreign pharmaceuticals, a FDA approval must be obtained. The approval stipulates fulfilment of several features, e.g. in regard to manufacturer's location, labelling, and list of active ingredients.[200]

Over the last years, the U.S. has repeatedly considered permitting parallel imports of pharmaceuticals. Most probably the country from where the parallel importation or drugs would happen would be the neighbouring Canada, sometimes also the EU and other countries. Thus, although the Congress passed in 2003 an act which would allow wholesalers and pharmacists to import foreign drugs if they were certified by the Secretary of Health and Human Services, then-Secretary Thompson refused to certify the Act.[201] Further in 2009, 20 US senators proposed an amendment into the US healthcare reform in order to permit wholesalers and pharmacies to import FDA-approved medicines from Europe, Canada, Australia, Japan and New Zealand. However, it was immediately opposed by the drug industry representatives and the FDA commissioner, although a spokesman from President Obama's administration indicated that Obama would work in order to pass a related proposal already in 2010.[202] Until now, such legislation has not been enacted.

Even if parallel importation would be enacted, it would probably be only a short-term solution as pharmaceutical companies can limit supplies abroad resulting to the initial situation - consumers have to pay high prices. Internet pharmacies, which can supply drugs at lower prices, have proven to be a safety, health, and counterfeit risk and without regulatory means do not offer a solution for lower prices to consumers in the US. High prices are caused by lack of national price controls, necessity of prescription medicines and R&D expenses in the US. In addition, commercial profits,

---

[198] This document can be found online at - http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactFDCAct/default.htm (last visited on 08 May 2014)

[199] 21 U.S.C. § 381(d)(1).

[200] Kyle, Margaret, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in,* B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 340 at 354 (2009)

[201] See Report on Prescription Drug Importation, Department of Health and Human Services (December 21, 2004), available at http://archive.hhs.gov/importtaskforce/Report1220.pdf.

[202] K. E. Maskus, Private rights and public problems, The global economics of intellectual property in the 21st century, 178-179 (2012)

marketing costs, price controls abroad, and political contributions affect the prices. Thus, it seems that many in the US do not believe parallel imports would ever occur.[203]

Refusal to deal

The most significant difference between EU competition law and US antitrust law is that the first prohibits *exploitative abuses*. EU law differentiates between exploitative and exclusionary market conduct, whereas US law does not; no one is prohibited from exploiting its lawfully acquired monopoly. The Sherman Act, Section 2, prohibits only monopolization (or attempts to monopolize). Thus, if customers are not competitors, the legal regime does not find a breach of law in case of refusal to deal, unless it can be regarded as an indirect way of monopolization. When refusing to supply competitors, such behaviour may infringe Section 2 of the Sherman Act provided that it aims at creating or expanding monopoly power. [204]

The Supreme Court held in *United States v. Grinnell Corp* that, "the offense of monopoly under Section 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the wilful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[205] The judgment of the Supreme Court held that the specific *intent* of the company in question has certain relevance but is not necessary for constituting a valid claim of Section 2. Thus, even its absence does not exclude that monopolization or its attempt is present.[206]

Another refusal to supply case was *Verizon Communications Inc*. v. *Law Offices of Curtis V. Trinko, LLP,*[207] where Verizon was claimed to breach Sherman Law. The Supreme Court unanimously delivered its Opinion as follows: "...[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue. Part of that attention to economic

[203] J. Ma, Lowering Prescription Drug Prices in the United States: are Reimportation and Internet Pharmacies the Answer? Southern California Interdisciplinary Law Journal, Vol. 15:345, 345 at 374 (2006)
[204] Csongor Istvan Nagy, Refusal to deal and the doctrine of essential facilities in US and EC competition law: a comparative perspective and a proposal for a workable analytical framework, European Law Review, E.L. Rev., 32(5), 664 at 666 (2007)
[205] United States v. Grinnell Corp,384 U.S. 563, 570-571 (1966)
[206] Csongor Istvan Nagy, Refusal to deal and the doctrine of essential facilities in US and EC competition law: a comparative perspective and a proposal for a workable analytical framework, European Law Review, E.L. Rev., 32(5), 664 at 666 (2007)
[207] Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, 124 S. Ct. 872 (2004), *rev'g* 305 F.3d 89 (2d Cir. 2002).

context is an awareness of the significance of regulation". The Supreme Court dismissed the claim stating that Verizon did not violate the Sherman Act reasoning that businesses are not obliged to aid competitors. For that matter, AG Jacobs referred to this same argumentation in his Opinion on *Syfait* emphasizing the necessity of considering the specific features of the industry in question when assessing whether a company's conduct breaches Article 101 TFEU. *Syfait* was discussed in detail in Chapter D. This example shows that the US Antitrust Law seems to be more enterprise-oriented than its European equivalent Competition law. Regarding refusal to deal in the EU and the US, the EU's approach is held to be more formalistic than in the US. Also, the EU approach emphasizes promotion of competition, leaving protection of companies' business choices aside and preferring short-term benefits to consumers instead of focusing on long-term efficiency gains.

There are many products that are sold in the US but are missing authorization on the Canadian market, the main source for unauthorized parallel importation into the US. Therefore, parallel imports from Canada would not concern a large set of products. For those products, which are available on both sides of the border, the effect of parallel trade depends on the fact whether pharmaceutical companies can legally restrict supplies to Canada. There have already been attempts to ration supply to pharmacies in Canada. Pfizer gave a warning to its distributors in Canada that it would stop supplying them if those products end up at someone exporting them out of Canada. GlaxoSmithKline decided to supply directly to retail pharmacies thus avoiding the threat of distributors or internet pharmacies selling its products across the border. Also other companies, such as AstraZeneca, Novartis, and Eli Lilly have taken measures to control or limit deliveries. Not surprisingly, above-mentioned rationing attempts have met heavy critics from antitrust authorities and lawmakers in the US.[208]

A company may unilaterally restrict supply without violating the Sherman Act, unless it is a monopolist. Regarding the pharmaceutical markets, the definition of 'a market' would generally be at a quite narrow level, e.g. a patented chemical. There are though already precedents, e.g. in several complaints against pharmaceutical companies where the Federal Trade Commission defined 'a pharmaceutical market' at a level of a formulation or molecule.[209] The antitrust

[208] Kyle, Margaret, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in,* B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 339 at 355 (2009)
[209] Kyle, Margaret, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in,* B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 339 at 355 (2009), see also, Abbott Labs. & Geneva Pharm., Inc., FTC Docket Nos. C-3945, 3946 (May 22, 2000).
Hoechst Marion Roussel, Inc. & Andrx Corp., FTC Docket No. 9293 (Mar. 16, 2000).

authorities have also used a broader definition of a market in a number of cases, but in order to risk violating the Sherman Act, the pharmaceutical companies would really need to coordinate their common actions. [210]

Moving from price discrimination to uniform prices through arbitrage seems to damage lower-price markets as a result of reduced supply. This potential was recognized in Canada. In 2006 several Canadian interest groups announced a joint statement, addressed to the opportunity of legal parallel trade. They requested an export ban, referring to a risk of supply shortages in Canada: "Canada needs to stop the cross-border drug trade before, rather than after, the United States legalizes drug imports from Canada. We need to protect Canadian patients and Canada's drug supply. As a responsible ally of the United States, the government must also act to protect Canadians and Americans against abuse of our system." [211]

III. Conclusions

We have learned from the earlier chapters that parallel trade in pharmaceuticals – as any other business – in under large protection and encouragement of the European Commission. The EU's goal to achieve a single market through free movement of goods is driving this development. Pharmaceutical companies aiming at limiting of parallel trade through restrictive agreements or refusal to supply (or deal) are judged under strict provisions of Article 102 TFEU, not giving much leeway to protect their investments and R&D contributions.

In the United States, in contrast, the protection of IPRs (patents) under the Sherman Law is strong enabling blocking of parallel imports of pharmaceuticals unless the patent owner has given permission to that. R&D and innovations are seen key promoters of the society and are thus preferred to benefits of lower consumer prices.

Schering-Plough Corp., Upsher-Smith Labs. & Am. Home Prods. Corp., FTC Docket No. 9297 (Mar. 30, 2001). Baxter Int'l, Inc. & Wyeth, FTC Docket No. C-4068 (Feb. 3, 2003).
Glaxo Wellcome plc & SmithKline Beecham plc, FTC Docket No. C-3990 (Jan.26, 2001).
62 Pfizer Inc. & Pharmacia Corp., FTC Docket No. C-4075 (May 27, 2003).
[210] Kyle, Margaret, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in,* B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 339 at 355 (2009)
[211] Ibid, 339 at 355

The main reasons for the different approaches of the two regions is that the EU competition law prohibits exploitative abuses, differentiating thus exclusionary and exploitative conducts, whereas US antitrust law does not. It means that a lawfully acquired monopoly can be exploited and parallel imports prevented by the IPR proprietor. It remains to be seen whether parallel imports of pharmaceuticals will be permitted in the US. Attempts to date have been unsuccessful.

It might be good to notify, that with the aim of mutual understanding and cooperation, the US Justice Department and the EU Commission have signed an agreement on information exchange in antitrust matters and mergers. However, starting points already differ: the US the anti-trust law (Sherman Law) gives the Justice Department the right to protect US companies' foreign trade, while the European Commission has no such power in relation to European companies. In accordance with the US Anti-trust Guidelines, the US is entitled to assert jurisdiction over foreign companies' activities abroad in case these activities impact negatively on US exports.[212]

The Americans have shown that in a free market environment where prices follow the law of supply and demand, pharmaceutical R&D has been successful. As already mentioned, the R&D investments in drugs are growing in the US much faster that in the EU. One could ask whether parallel trade in Europe has contributed to this progress or is it a result of other reasons. The Europeans have to gain back their advantage and that seems to succeed only by taking more effect based approach towards parallel trade.

[212] P. W. Grubb & P. R. Thomsen, Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law, Practice, and Strategy, 503 (2010)

G. View of Competition Authorities

The Commission published a communication on parallel imports of pharmaceuticals in 2003[213], which draws guidelines on how the case law of the EU Courts in regard to parallel imports should be interpreted in connection with national actions. However, this Communication was more focused on free movement and exhaustion issues. After that, the Commission has been dealing with the parallel trade issues mainly in case law. The interest of the Commission in matters concerning competition rules in the pharmaceutical sector has long been focused on the entry into the market of the parallel imported drugs and competition between original and generic drugs. However, in the near future, after several years, the Commission authority has indicated that it would start reconsidering parallel imports of pharmaceuticals and potential restrictions to competition related to these activities.[214] It shows that the issues with pharmaceutical parallel trade have remained silent thus not disappeared.

The important role of the Commission and the National Competition Authorities in Competition law cases relating to pharmaceutical parallel trade triggered the idea for questionnaires to the relevant authorities. The aim of this research method was to find out how the authorities see the relevant issues under Competition law cases discussed in earlier Chapters. Further, this would also allow to draw some conclusions for the future implications in Chapter H.

I. The View of the EU Commission

The Directorate General of Competition is a unit of the European Commission.[215] The questions were presented to Mr Borja Castromil[216], a case handler at DG Competition.

---

[213] COM/2003/839final, Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted

[214] S. Valliluoto Lääkehuollosta lääkemarkkinoihin – Arvoketju ja Sääntely, Kilpailuviraston Selvityksiä 2/12 at 57; Informa: EU Pharmaceutical Law Forum, DG Competition Blaž Visnar, 22–23.5.2012 Brussels

[215] http://ec.europa.eu/dgs/competition/index_en.htm
The European Commission, together with the national competition authorities, directly enforces EU competition rules, Articles 101-109 of the Treaty on the Functioning of the EU (TFEU).Within the Commission, the Directorate-General (DG) for Competition is primarily responsible for these direct enforcement powers.

[216] Mr Borja Castromil, Unit E-1-Antitrust, Pharma and Health Services, phone +32 229 64760, borja.castromil@ec.europa.eu, phone discussion on 18 February 2014 and on 7 April 2014.

The first question presented to DG Competition is close to the scope of this thesis. It raises the possible need of changes in regard to treatment of the pharmaceutical sector on the grounds of its special nature. Mr Castromil answered referring to some recent judgments, such as *GSK v. Commission; Syfait and Sot Lelos.* He emphasized that the Commission respects the Court's decisions and acknowledges that pharmaceutical industry is a specific sector, although competition law applies also to that sector. The answer included the main cases studied, thus they seem to be quite relevant.

The second question was about the Commission's possible considerations on further regulatory measures for defining the right balance between efficiencies and anti-competitive acts based on *GSK case* where the ECJ upheld the General Court's finding that dual pricing could benefit from an exemption under Article 101(3), provided that efficiencies outweigh its anti-competitive acts. The Commission acknowledges that there is uncertainty with dual pricing practice and some uncertainty issues raised in *Glaxo* which require the Commission's action at some point. The Commission will take into account the Court's decision, especially in regard to the possible exemption under Article 101(3) TFEU. As it was though not an order, the Commission has not published any documents or statements so far. However, two cases on dual pricing practices are now in the Spanish Supreme Court with Pfizer and other major drug companies involved. The decision was awaited already in 2013 but was delayed. The Commission hopes to have the decision this year. It would be an important decision also for Commission.

The third question concerned the status of the Commission-initiated probe or questionnaire on parallel trade in medicines from 2012. Mr Castromil answered, that after *Glaxo* in March/April 2012, the Commission sent an inquiry to the Spanish wholesalers. The Commission has the right to request information under Article 18 of the Commission regulation 1/2003.This was though not a pharmaceutical sector inquiry as in 2009 about generic medicines. The replies are received, but the Commission has not published anything after the study.

The fourth question about EU-level harmonization of prices and possible challenges seen by the Commission in regard to competition was answered decisively; there are no current initiatives at DG Competition. Further, the Commission does not have an opinion of this. In case of new initiatives, also other service areas would be involved, such as DG Health and Services and DG Enterprise. This is more an internal market issue. DG Competition has discussed with the industry

pricing policies of pharmaceuticals. The Commission has not published any guidelines or initiatives about the subject.

The fifth question was about shortages of prescription medicines and the Commission's reaction on the UK Government's All Parties Parliamentary Group's initiative on preventing exports of prescription medicines in order to protect public health. Also, APPG's joint call for actions to governments, EU regulators and the Commission was discussed[217]. The Commission was asked whether a Member State could block imports or exports and on which grounds. The DG Competition was not aware of such initiatives and thus did not have any opinion. According to DG Competition, the supply shortages are part of greater discussion and may be caused by several reasons. If a Member State is banning parallel imports or exports, it is not a competition law issue and thus DG Competition has no opinion of it. The supply issues are under the competence of DG Health and Consumers, based on Article 81 of the Directive 2001/83. Unfortunately, the question was not forwarded to that DG due to lack of time.

An evaluation of current shortages in a number of EU Member States was recently made by EAEPC.[218] It found that there are several reasons for drug shortages and potential solutions available for improving the situation. However, the focus should be on patients and not only on legal, political and commercial aspects. As shortages are not limited geographically and follow certain causality, solutions need to be coordinated locally. A dialogue between all stakeholders should thus start in order to prevent shortages to escalate.

The last – and maybe most interesting – question was about current issues of parallel trade in pharmaceuticals. Mr Castromil gave his personal opinion of this, as the Commission has no official view on the matter. According to him, the following topics would be interesting:
1. Due to the economic crisis in Europe, the situation of the pharmaceutical industry has got more difficult in terms of parallel trade, but of course the outcome of this will depend on the general market situation so the Commission will follow this development.

[217] The representative organizations for European community, hospital and industrial pharmacists have issued a joint call for action by Governments, regulators and the European Commission to tackle the growing problem of medicines shortages (Joint Press Release 16 May 2013).
[218] Information reproduced at http://www.eaepc.org/medien/an-evaluation-of-medicines-shortages-in-europe-with-a-more-in-depth-review-of-these-in-france-greece-poland-spain-and-the-united-kingdom.pdf (last visited 12 February 2014)

2. International reference pricing[219] and how it affects parallel trade.

II. The View of National Competition Authorities – Example of Finland

One of the objectives of this thesis was to find out the view of a national authority dealing with competition and consumer related issues on the status of parallel imports of pharmaceuticals. In connection with this, a questionnaire with eight detailed questions was sent to the Finnish Competition and Consumer Authority (FCCA). FCCA is a legally mandated authority with competition and consumer related responsibilities, such as implementation of competition and consumer policy and enforcement of national and EU competition regulation. Furthermore, FCCA ensures appropriate market performance and secures consumers' legal and financial rights. It also gives proposals to other state officials and governmental institutions for promotion of competition and removal of obstacles to it, and takes part in international co-operation related to competition policy.[220] According to a recent international comparison, Finland has the most effective competition legislation, i.e. it is strongly promoting competition. The main national regulations were brought into compliance with EU competition law already in 2004.[221]

One of the questions was re-addressed to the Finnish Medicine Agency (Fimea)[222] for more detailed answer and two questions to the Pharmaceuticals Pricing Board (Hila).[223]

The questions addressed to FCCA with the agency's consequent answers, given by senior researcher Mr Jan Nybondas,[224] try to draw a picture of the Finnish competition authority's standpoint on the effect of parallel imports of pharmaceuticals on promotion of competition, as well as on consumer benefits, including possible price reductions in a long term. As a starting point, on the question concerning possible different opinions of FCCA and the EU Commission in regard to parallel imports of pharmaceuticals, FCCA answered that there is no such difference of opinions in this matter. This confirms the preconception of the similar opinions of FCCA as an

---

[219] See, http://ec.europa.eu/health/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf
[220] http://www.kkv.fi/Page/71661344-b9e9-49f2-bdc0-c533afea001a.aspx
[221] http://www.kkv.fi/Page/5abb4555-6445-4e0a-8011-e7efd59ef6d3.aspx?groupId=8b466af6-1441-4cdc-907d-fc93cca74ac9&announcementId=40c36c0f-100b-44d3-bf29-ccf3bd714df2
[222] http://www.fimea.fi/
[223] http://www.stm.fi/en/ministry/boards/pharmaboard/
[224] Jan Nybondas, FCCA, jan.nybondas @kkv.fi, answers received by email 8 November 2014

agency fully committed to the EU approaches regarding parallel imports as a competition promoter.

The second question concerning the particularities or special features of pharmaceuticals market and whether these features are supported was answered shortly and concisely: the access of a parallel imported product into a country's market is dependent on the country specific price regulation and reimbursement systems of Member States. Thus, a wider scope of the answer was brushed aside and the answer focused on practical effects of the specific nature of the pharmaceutical sector in general. The third question about the price harmonization of pharmaceuticals at EU/ETA level generated somewhat cautious discussion about the political nature of harmonization, as well as its complexity in a situation where citizens are not equal in regards to buying power. Finally, FCCA answered that they do not have a standpoint in this matter.

Next question was probably closest to FCCA's competences and passions as it was answered in detail. The agency answered that they have given their opinion on restrictions of parallel imports of medicines already in 2012 when they turned to the Finnish Medicine Agency (Fimea) with an initiative stating that access to parallel imported pharmaceuticals is being prevented. In its statement, FCCA noted that substitution of medicines is not working in practice as interchangeable medicines are not always offered by the pharmacies and they are not included in the same reference price[225] group with the original products.[226] More precisely, FCCA thinks that Fimea should take measures in order to ensure that substitution of medicines promotes a full-scale competition prescribed by the Medicines Act.[227] In practice, there should be an online monitoring system which shows that the cheapest interchangeable pharmaceuticals are indeed ordered, stored and delivered. In addition, FCCA proposed that *legislation regarding the priority of the most inexpensive inter-changeable medicines in the pharmacies' drug sales should be clarified*.[228] According to FCCA, the earnings logic of pharmacies should be such that they had a stimulus to offer the cheapest drugs

[225] Reference price system for prescription medicines entered into force in 2009 to complement drug substitution. Reimbursement is paid to the patient based on the reference price regulated by social insurance law so that for each reference group is defined a maximum price.

[226] In Finland, approximately 49 % of all medicinal products having marketing authorization and meant for humans are subject to substitution. The total number of interchangeable pharmaceuticals is 7865, see at: http://www.fimea.fi/ajankohtaista/ajankohtaista_uutissivu/1/0/keskenaan_vaihtokelpoisten_laakevalmisteiden_luettelo_1_1_-31_3_2014

[227] The Finnish Medicines Act, Lääkelaki 395/1987 with amendments

[228] Emphasis added.

to the patients. Finally, inclusion of parallel imported pharmaceuticals into the reference price system in the full extent should be reconsidered.[229]

Concerning the question about parallel importation's role in increasing competition and decreasing prices (which have been main arguments for promotion of parallel imports of pharmaceuticals), FCCA gave quite a moderate estimate, in parallel referring to the reasons described in the previous answer. Thus, as the market share of parallel imports of pharmaceuticals in Finland is only 1 - 2 %, the effect on the retail prices of pharmacies is insignificant. Slightly higher influence parallel imports have had on purchases of medicines by hospitals. Mrs Kaarina Koskela[230], a lawyer at the Pharmaceuticals Pricing Board (Hila), said that there is no statistics available on how parallel imports have affected the prices or competition. Recently, a study by the Eastern Finland University together with the Social Insurance Institution of Finland was made concerning use of generic medicines. Generic substitution is beyond the scope of this thesis, but offers certainly good material for another research.

Regarding the worries about shortages of, in particular, prescription drugs, and the possible relation between parallel trade and shortage, FCCA advised to turn to pharmaceutical authorities answering though that according to their knowledge no shortages because of parallel imports had occurred.

The answer to this question given by Mrs Merja Laakso[231], a coordinator of marketing authorizations at Fimea, was rather general. They consider that – perhaps more than parallel imports – generic substitution and the reference price system have affected the availability of pharmaceuticals. The Pharmaceuticals Pricing Board noted that serious shortages have not occurred in Finland and, in fact, the availability rate is very high, 99%.
Recently, there have been worries in the Finnish press about wholesalers' inability to supply some painkillers to pharmacies. Many of the availability issues are related to the fact that Finland is very dependent on importation of drugs. Also, small peripheral markets, such as Finland receive 'spot' batches covering the demand only for a couple of weeks. [232]

---

[229] Currently a parallel imported product is included in the price reference list if there is no generic medicine available in addition to the original product.
[230] Kaarina Koskela, Hila, kaarina.koskela@stm.fi, answers received by phone on 7 May 2014
[231] Merja Laakso, Fimea, merja.laakso@fimea.fi, answers received by email on 24 March 2014
[232] http://yle.fi/uutiset/laakkeiden_saanti_apteekkeihin_kangertelee_-_kipulaakkeita_loppunut_tukusta/6767044?ref=leiki-uu 10.08.2013

Concerning the slightly ‘provocative’ question about parallel importation as a threat to national R&D and innovations of drugs, FCCA took a clear standpoint: they do not believe this kind of threat exists. However, parallel imported products together with a strong competition accompanying them can create a more challenging business environment for the originator manufacturers, which will decline their assets for R&D unless new breakthroughs occur enabling to increase the amount of patent protected products. The last question on FCCA’s possibilities to impact on finding a balance between EU competition law and IPR in the interface of parallel importation of pharmaceuticals was quite fundamental but FCCA managed to create a pragmatic answer to it. Thus, it referred to the Commission’s and ECJ’s efforts in finding a balance in the situations where a pharmaceutical company has tried through special arrangements to block deliveries to a Member State with the aim of affecting the amount of parallel trade. FCCA can express its views in the consultative meetings to matters concerning parallel trade and thus try to contribute to the Commission’s resolutions.

H. Answer to the Thesis Question and a Way Forward

This thesis aimed at answering the following questions 1) How the special nature of the pharmaceutical sector is being considered when assessing dual pricing under Article 101 TFEU and refusal to supply under Article 102 TFEU?; 2) What is the effect of parallel trade on pharmaceutical prices, on innovations, and on consumer welfare?; 3) And finally, taking into account the current legal and economic context of parallel trade, should the pharmaceutical sector be given a special position under Competition law?

As a hypothesis I suggested that the environment of free market, the pro-competitive free movement of goods creates benefits to the consumers by equalizing price differences. However, the pharmaceutical market makes an exception in the EU; it is not a free market but is distorted by various price regulations and controls by national authorities of Member States. In these circumstances, restrictions to parallel trade should be analyzed taking into account the specific characteristics of the sector. The impact of parallel trade on consumer welfare should be weighed against the special nature of the sector.

This study has already shown that pharmaceutical industry has several special characteristics which should be taken into account when taking decisions concerning competition law, both regarding case law and regulatory actions. However, the question whether the pharmaceutical industry should be given a special position in the cases on parallel importation, is controversial.
In *Sot Lelos* the Court did not give any special treatment to the pharmaceutical industry, however it clarified that manufacturers could protect their commercial interests when it is considered proportionate and reasonable. However, the exact scope of this protection is still uncertain.

The Court's stance to restrictions was not surprising taking account the earlier case law and the goal of achieving a single market with its competition objectives. The opinion of AG Jacobs in *Syfait* differed significantly from the traditional approach of the Court. The argumentations of AG Jacobs on the recognition of the special position of the pharmaceutical sector were credible. He based his thoughts to the pervasive price regulation and innovation aspects of the sector.

In *Glaxo*, both Courts confirmed that the Commission erred, when it did not assess the request for an exemption in a proper manner, i.e. did not consider the impact of parallel trade on innovation activities. However, this may be understood as the Commission has always supported parallel trade in the name of free trade.

The results of various studies indicate that parallel trade in pharmaceuticals does not considerably affect the prices and thus not offer significant benefits to consumers. Due to the fact that Member States are entitled to determine price levels, the price effect of parallel trade is not necessary in order to gain sufficient savings. However, it has been established that parallel trade has an impact on the earnings of manufacturers. These profit losses may lead to the reduction of innovations as the share of R&D is significant in the pharmaceutical sector. This argument was presented by manufacturers in each case under competition law on restriction of parallel trade. Furthermore, pharmaceutical producers have argued that they are left with the only alternative: medicines will not be launched at all in the markets in such countries where earnings would remain low because of parallel trade. From welfare policy point of view one could ask what is more important: consumer benefits from possible price reductions as a result of parallel trade or consumers benefits from R&D of new medicinal products and rapid launch of new medicines?

Based on the relevant studies on the issue, consideration of legal aspects of the pharmaceutical sector should emphasize its special features as the EU pharmaceutical market is not a free market with a standard demand and supply mechanism due to governmental price controls and regulations. Referring to the above mentioned factors, parallel imports benefit consumers only little and public reimbursement systems fairly modest, at most. However, EU competition rules and the Commission are encouraging parallel trade in pharmaceuticals based on the expectations of benefits to customer welfare, in particular. The research results show that the profit is left mainly at the parallel importers, whose business does not enhance total welfare or add any value to the functioning of pharmaceutical market. In fact, this business is rather creating inefficiencies which in a normal market economy would not survive without price regulations favoring it. The current model, where governmental price and profit regulation, presumption of free competition as a basis for regulation and promotion of parallel imports coexist, is much too challenging for research-based pharmaceutical companies.

The effects of parallel trade, both positive and negative, should be taken more widely into consideration when assessing the drug companies' behavior towards parallel trade. The positive impact of new drugs on the national economy is significant: drugs both treat and prevent from diseases and are usually cheaper than other treatments. An important step to a right direction was GlaxoSmithKline's dual pricing case, and the EU courts should continue on that way in order to encourage companies to innovate enabling resources for R&D and protection of the innovation. EU legislators should have a deeper look at today's pharmaceutical market structure with a clearly political statement on the status and development of the industry instead of giving EU Courts control over issues requiring large economic argumentation.

A Way Forward

Parallel trade in pharmaceuticals should be protected only the extent where it promotes competition and consumer welfare. Due to the national regulation, the impact of parallel trade on price competition has been questioned. In addition, when considering its possible negative effect on innovations, consumer welfare benefits may not be as large as has been interpreted earlier. For these reasons, there should be further studies of the sector in order to find out the final effects on welfare. In 2009, the Commission organized a pharmaceutical sector inquiry, thus merely regarding the launch of generic drugs. A similar research on the impact of parallel trade in the pharmaceutical sector would be necessary. The study should be carried out, specifically, by an independent body. As mentioned in the answer by the DG Competition to the questionnaire, the Commission performed an inquiry on parallel trade to Spanish wholesalers in 2012. However, this study was an internal study within the Commission, and nothing of the results has been published yet. Currently, the Commission seems to focus on the entry on market of generic medicines, which manufacturers have attempted to prevent. Obviously, parallel importation will continue to exist and there will be attempts to block it the same way as earlier, perhaps only with different strategies. As was noted by GSK in *Sot Lelos*, supporting parallel trade may lead to a situation where the launch of new medicines on certain low-price Member States is delayed probably resulting in fatal consequences to consumer welfare.

The impact of parallel trade in pharmaceuticals from the view of Competition law in the context of the welfare of consumers and research-based companies' incentive to innovate is largely disputed. Exemption under Article 101(3) TFEU provides some tools to mitigate these disputes and balances the situation where parallel traders are practically the only winners, although the

legislator's aim was to emphasize the end consumer benefit as the main driver for encouraging parallel trade. Pharmaceutical R&D companies seem to lose most: their profits decline and incentive to put efforts to development of new and more efficient drugs decreases. In order to improve the situation, the mind-set of all stakeholders involved should be changed to more consumer-benefitting direction. Thus, the assessment of the exemption under Article 101(3) and the objective justification of Article 102 TFEU should be revised taking into account the importance of effects on consumer welfare.

Regarding the intersection between *Glaxo* case and Article 101(3), the Commission has stated that they should take actions on the basis of the judgment, since it was clearly stated by the Courts that Commission erred when it did not check the grounds of the request for an exemption. The Commission has not explored the specific nature of the pharmaceutical sector, where national price and profit controls and reimbursement regulations of Member States occur at different levels and where thus the standard demand and supply scheme does not work, as free competition market would expect. So, it seems that there are uncertainties, which would need a statement also from the Commission. The Commission now has the Courts' guideline to follow; time will tell how the Commission will act on this.

J. Conclusions

Parallel trade in pharmaceutical sector is flourishing in the EU with the encouragement by the Commission and the Courts emphasizing the principles of free movement of goods and single market integration. The research-based pharmaceutical industry, instead, considers that parallel traders (the 'free riders') are affecting negatively companies' ability to invest in R&D as earnings decrease. Therefore, these companies try to prevent parallel importation of their original drugs.

Contradictory interests of IPR owners and the single market goals have led to disputes before the ECJ. *Consten & Grundig* started a practice by the EU Courts of dividing the existence and exercise of IPR. The mere existence is not anticompetitive as such; only the exercise might prove to be against EU Competition law.

The general approach towards restrictions to parallel trade has been strictly forbidding. However, the recent case law in pharmaceutical sector indicates that a more economic approach considering the special features of the pharmaceutical sector and the effects of parallel trade are taking place. Whether the new approach can be promoted in Competition law, remains to be seen.

In accordance with the EU legislation, pharmaceutical manufacturers and wholesalers are obliged to secure supplies of medicinal products to pharmacies and patients. The Commission controls possible anticompetitive conduct of drug companies which would result in price increase of pharmaceuticals. The national authorities regulate health care expenses of the Member States by determining price levels. In addition, only those medicines can enter the market, which are in the reimbursement list of national health care funds. Regulation of price and profit levels are claimed to be one of the reasons why the European drug industry is losing competition to US and other markets, especially in regard to R&D of new drugs.

The United States have shown that in a totally free market environment of business with the law of supply and demand, pharmaceutical R&D has been successful. One evidence of this is the fact that pharmaceutical R&D investments are growing in the US much faster that in the EU. Whether parallel trade in Europe has contributed to this negative evolution, is a question to be answered.

Meanwhile, the Europeans should gain back their good position in R&D. That seems to succeed only by taking more effect-based approach towards parallel trade.

The specificity of the pharmaceutical sector lies on innovations which create the basis for the research-based industry. The largest share of the sector's assets are expensed to R&D. Pharmaceutical companies refer to special characteristics of the industry, including price intervention by Member States, obligation to supply, and R&D spending, in cases brought against them under EU Competition law. Thus, GSK referred to these factors in *Syfait*. According to AG Jacobs, when reasonable and proportionate, the special features of the industry would justify a restriction to parallel trade. He was willing to accept the special position of the industry. However, no judgment was given in *Syfait* and his view was rejected in *Sot Lelos*.

In *Sot Lelos,* refusal to supply existing customers was considered as breach of Article 102 TFEU. According to the ECJ, the producer is obliged to supply ordinary orders, though not defining 'ordinary'. Means for protecting company's commercial interests are allowed to a reasonable and proportionate extent in case they are not aimed at reinforcing dominance. However, the Court was not willing to consider the innovation factors as a basis for protecting those interests.

In dual pricing case of *Glaxo,* the Commission stated that limiting parallel trade constitutes a restriction by object. However, the CFI challenged the decision on the grounds that the pharmaceutical industry differs from other sectors and thus no restriction of competition by object under Article 101(1). The CFI though found a restriction by effect. Furthermore, it criticized the Commission's decision not to give an exemption under Article 101(3).

As discussed earlier, pharmaceutical sector was not given any immunity from the rules under Competition law in *Glaxo* and *Sot Lelos.* In *Glaxo*, however, the Court recognized that the specificity of the pharmaceutical market and efficiency claims should have been assessed in in relation to the exemption under Article 101(3). The issue of the possible negative effects of parallel trade on investments remains open but, in general, the judgments do not recognize the special nature of the pharmaceutical sector.

When analysing the influence of parallel trade, long-term effects came up. Even if it generates short-term economic benefits, these benefits shall be in proportion with damage caused to the other

parties involved. According to some studies, parallel trade creates at most moderate savings to health insurance systems, whereas negative effects are increasing. Parallel distributors seem to be the main beneficiaries, while consumer benefits and price competition are not coming true. This makes parallel trade an inefficient way of cost savings.

Provided that price differentials are passed on to prices the consumers have to pay, consumer benefits may take place. On the other hand, delays in launch of new drugs due to decreased earnings affect negatively on consumer welfare. Also, drug shortages may cause concerns to consumers thus decreasing welfare. All these factors shall be taken into account when considering the possibility of giving the pharmaceutical sector a special position in parallel trade cases.

Summary

This thesis examined the special characteristics of the pharmaceutical industry in parallel trade cases under EU Competition law. For this purpose, I was focusing on restrictions deriving from dual pricing schemes and a dominant undertaking's refusal to supply pharmaceuticals. Furthermore, I tried to answer the following questions: How the special nature of the pharmaceutical sector is being considered when assessing dual pricing under Article 101 TFEU and refusal to supply under Article 102 TFEU? What is the effect of parallel trade on pharmaceutical prices, on innovations, and on consumer welfare? And finally, taking into account the current legal and economic context of parallel trade, should the pharmaceutical sector be given a special position under Competition law?

The structure of the thesis followed this order. Chapter A contains the introduction to the research, the aims and research questions and the methods used to complete this study. Chapter B examined the relationship between intellectual property rights and EU Competition policy in parallel trade, especially in pharmaceuticals. Chapter C introduced the European pharmaceutical market and the special features of the market. It studied the regulatory measures in the market and the importance of innovation in the industry. Chapter D presented a case study on parallel trade of pharmaceuticals in EU Competition law, more specifically how EU Competition law treats the strategies of dual pricing and refusal to supply as means of manufacturers to prevent parallel trade. Further, it discussed how the special characteristics have been taken into account in the assessment under Competition law. Chapter E analyzed the economic effects of parallel trade on prices and on R&D in the light of the case law dealt in the previous chapter.

Chapter F compared the different approaches to parallel trade in pharmaceuticals in the EU and the United States. Here I tried to find out whether there is something to be learnt from each jurisdiction. Chapter G presented the current policy arguments by the European Commission authorities, specifically the authorities of DG Competition, and the Finnish Competition and Pharmaceutical authorities. The answers to the questionnaires reflect to the appropriate case law presented in the earlier chapters. Chapter H provided an answer to the research questions and a way forward in the current issue.

In the environment of free market, the pro-competitive free movement of goods creates benefits to the consumers by equalizing price differences. The pharmaceutical market is, however, different: it is a market distorted by various regulations and controls by Member States. Thus, it does not present a free trade environment with standard demand and supply rules. In these circumstances, when assessing companies' attempts to restrict parallel trade, the specificity of the sector should be considered. Furthermore, the effects of parallel trade on consumer welfare should be assessed against the special nature of the sector. The uncertainty of the Competition law issues on parallel trade made this analysis challenging but interesting.

List of Sources

I. Books

Alkio, Mikko & Wik, Christian, Kilpailuoikeus (2009)

Anderman, Steven & Schmidt Hedvig, EU Competition Law and Intellectual Property Rights – The Regulation of Innovation, Second Edition, Oxford University Press, (2011)

Anderman, Steven, *The new EC competition law framework for technology transfer and IP licensing,* Research handbook on intellectual property and competition law in Drexl, J. (Ed.), 109-141, Edward Elgar Publishing (2008)

van Bael, Ivo & Bellis, Jean-Francois, Competition Law of the European Community, Kluwer Law International (2010)

Cornish, William R. Llewelyn, David and Aplin, Tanya, Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights (2010)

Desogus, Claudia, Competition and Innovation in the EU Regulation of Pharmaceuticals:
The Case of Parallel Trade, Intersentia (2011)

Ezrachi, Ariel, EU Competition Law, an Analytical Guide to the Leading Cases, Oxford: Hart Publishing (2012)

Graig, Paul, de Búrca, Grainne, EU Law: Text, Cases and Materials (2011)

Grubb, Philip W & Thomsen, Peter R., Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law, Practice, and Strategy, 503 (2010)

Hancher, Leigh, *The EU pharmaceuticals market: parameters and pathways in* Mossialos, E. (Ed.), Health Systems Governance in Europe: The Role of European Union Law and Policy, Cambridge University Press, 635-682 (2010)

Hancher, Leigh & Sauter, Wolfgang, EU Competition and Internal Market Law in the Health Care Sector, Oxford University Press (2012)

Hays, Thomas, Parallel Importation under European Union Law, London, Sweet & Maxwell Ltd, (2004)

Joukas, Janne, *Lääkevalmisteiden uudelleenpakkaaminen Euroopassa in* K. Sorvari (Ed.), Teollisoikeudellisia kirjoituksia XI, 25-143, Turun Yliopisto (2010)

Keeling, David T., Intellectual Property Rights in EU Law: Volume 1: Free Movement and Competition Law, Oxford University Press (2003)

Kur, Annette & Dreier, Thomas, European Intellectual Property Law: Text, Cases & Materials, Edward Elgar Publishing (2013)

Maskus, Keith E., Private Rights and Public Problems, The Global Economics of Intellectual Property in the 21st Century, United Books Press, Inc. (2012)

Montesa Lloreda, Aitor, *Parallel Trade in the Pharmaceutical Industry from a Competition Point of View*, in Kanninen, Heikki & Korjus, Nina & Rosas, Allan (Eds.), EU Competition Law in Context, Oxford, Oregon, Portland, Hart Publishing, (2009)

Stothers, Christopher, Parallel Trade in Europe, Intellectual Property, Competition and Regulatory Law, Oxford and Portland, Hart Publishing (2007)

Tervo, Kalle, *EY:n kilpailuoikeuden soveltuvuus ETA:n ulkopuolelta tulevaan rinnakkaistuontiin in* A. Saarnilehto (Ed.), Teollisoikeudellisia kirjoituksia VII, 123-144, Turun yliopisto (2006)

Tritton, Guy, Intellectual Property in Europe, Sweet & Maxwell London, (2008)

Turner, Jonathan D.C., Intellectual Property and EU Competition Law, New York: Oxford University Press (2010)

Waelde, Charlotte, Contemporary Intellectual Property Law and Policy, Oxford University Press (2014)

Whish, Richard, Competition Law, Oxford University Press (2009)

Whish, Richard & Bailey, David, Competition Law, 7th edition, Oxford University Press (2012)

II. Articles

Aitlahti, Tiina, *Lääkevalmisteiden dokumentaatiosuoja. Kannustin uusien lääkehoitojen kehittämiseen*, IPR Info 3/2005, Reproduced online at http://www.iprinfo.com/julkaisut/iprinfo-lehti/lehtiarkisto/2005/IPRinfo_3-2005/fi_FI/laakevalmisteiden-dokumentaatiosuoja/, (last visited on 8 February 2014)

Avgoustis, Ioannis, *Parallel imports and exhaustion of trade mark rights: should steps be taken towards an international exhaustion regime?* European Intellectual Property Review, 34(2), 108-121 (2012)

Cole, Matthew, *Pharmaceuticals and competition: first strike to the Commission?* European Competition Law Review 34(5), 227-232 (2013)

Coscelli, Andrea, Edwards, Geoff & Overd, Alan, *Parallel trade in pharmaceuticals: more harm than good?* European Competition Law Review, 29(8) 490-492 (2008)

Dawes, A., *Neither Head nor Tail: the Confused Application of EC Competition Law to the Pharmaceutical Sector*. European Competition Law Review 27(5), 269-278 (2006)

Dostert, Anne: *Parallel Trade in Pharmaceutical Products Within the Internal Market: The Recent Glaxo Judgment of the E.C.J.*, The Columbia Journal of European Law Online (16), 25-29 (2009) Reproduced online at http://www.cjel.net/online/16_1-dostert/, (last visited 8 May 2014)

R. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 Ford. L. Rev. 477 (2003)

Enchelmaier, Stefan, *The inexhaustible question - free movement of goods and intellectual*

property in the European Court of Justice's case law, 2002-2006, International Review of Intellectual Property and Competition Law 38(4), 453-470 (2007)

Feros, Anna, *Free movement of pharmaceuticals within the EU - should rights be exhausted regionally?* European Intellectual Property Review 32(10), 486-497 (2010)

Hollist, Aidan & Ibbott, Peter, *How Parallel Trade Affects Drug Policies and Prices in Canada and the United States.* American Journal of Law & Medicine (32), 193-217 (2006)

Graf, Thomas & Hallouet, Stephanie, *Dominant companies may not refuse ordinary orders with the aim of restricting parallel trade: the ECJ judgment in GlaxoSmithKline AEVE*, European Competition Law Review, 30(4), 194-197 (2009)

Ganslandt, Mattias & Maskus, Keith E., *The Price Impact of Parallel Imports in Pharmaceuticals: Evidence from the European Union*, Journal Health of Economics 23(5), 1035-1057 (2004)

Grassie, Gill, *Parallel imports and trade marks - where are we? Part 1*, European Intellectual Property Review, 28(9*)*, 474-479 (2006)

Grigoriadis, Lazaros G., Application of EU Competition Law in the Pharmaceutical Sector: the Case of Parallel Trade, European Business Law Review 25(1), 141-201 (2014)

Kanavos, Panos & Costa-i-Font, Joan, *Pharmaceutical parallel trade in Europe: stakeholder and competition effects.* Economic Policy 20(44), 751-798 (2005)

Kanavos, Panos & Vandoros, S, *Competition in prescription drug markets: is parallel trade the answer?* Managerial and Decision Economics, vol. 31(5), 325-338 (2010)

Kanavos, Panos, Gross, David & Taylor, David, *Parallel Trading in Medicines: Europe's Experience and Its Implications for Commercial Drug Importation in the United States* (2005) Reproduced online at - http://assets.aarp.org/rgcenter/health/2005_07_trade.pdf (last visited on 2 May 2014)

Kyle, Margaret, *Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy in*, B. Hawk (Ed.), International Antitrust Law & Policy: Fordham Competition Law, 339-358 (2009). Reproduced online at http://margaretkyle.net/IntlAntitrust.pdf, (last visited on 9 May 2014).

Liberatore, Francisco, *UK calls for ban of parallel trade of prescription medicines - what are the EU competition law implications?* European Competition Law Review 34(4), 189-196 (2013)

Ma, Jonathan, *Lowering Prescription Drug Prices in the United States: are Reimportation and Internet Pharmacies the Answer?* Southern California Interdisciplinary Law Journal, Vol. 15:345, 345-375 (2006). This article is reproduced online at - http://www-bcf.usc.edu/~idjlaw/PDF/15-2/15-2%20Ma.pdf ;last visited 09 May 2014

Maskus, Keith: *The curious economics of parallel imports*, WIPO Journal 2(1), 123-132 (2010) This article is reproduced online at - http://www.wipo.int/export/sites/www/freepublications/en/intproperty/wipo_journal/wipo_journal_2_1.pdf (last visited 6 April 2014)

Moore, Julia A., *Parallel Trade, Unparallel Laws: An Examinations of the Pharmaceutical Parallel Trade Laws of the United States, the European Union and the World Trade Organization*, Richmond Journal of Global Law and Business, 77-92 (2006)

Nagy, Csongor I., *Refusal to deal and the doctrine of essential facilities in US and EC competition law: a comparative perspective and a proposal for a workable analytical framework*, European Law Review, 32(5), 664-685 (2007)

Petrucci, Carlo, *Parallel trade of pharmaceutical products: the ECJ finally speaks - comment on GlaxoSmithKline*, European Law Review 35(2), 275-286 (2010)

Tsouloufas, Georgios, *Limiting pharmaceutical parallel trade in the European Union: regulatory and economic justifications.* European Law Review 36(3), 385-404 (2011)

Turner-Kerr, Peter, *Finally a bit of clarity for pharmaceutical companies; but uncertainties remain: judgment of the ECJ in Sot Lelos kai Sia EE v GlaxoSmithKline AEVE*, European Competition Law Review, 30(2), 57-60 (2009)

III. Internet

http://www.kilpailuvirasto.fi/cgi-bin/suomi.cgi?luku=uutisarkisto&sivu=dyn/uutiset&nayta=arkisto&vuosi=2012 (last visited 16 May 2014)

http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm, (last visited on 28 April 2014)

http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf, (last visited on 28 April 2014)

http://isites.harvard.edu/fs/docs/icb.topic90998.files/ramsey-pricing.pdf, (last visited on 2 May 2014)

http://www.ema.europa.eu/ema/, (last visited on 4 May 2014)

http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactFDCAct/default.htm (last visited on 08 May 2014)

http://www.imi.europa.eu/, (last visited 13 April 2014)

http://ec.europa.eu/dgs/competition/index_en.htm (last visited 12 May 2014)

http://www.eaepc.org/medien/an-evaluation-of-medicines-shortages-in-europe-with-a-more-in-depth-review-of-these-in-france-greece-poland-spain-and-the-united-kingdom.pdf (last visited 1 March 2014)

http://www.kkv.fi/Page/71661344-b9e9-49f2-bdc0-c533afea001a.aspx (last visited 12 January 2014)

http://www.kkv.fi/Page/5abb4555-6445-4e0a-8011-e7efd59ef6d3.aspx?groupId=8b466af6-1441-4cdc-907d-fc93cca74ac9&announcementId=40c36c0f-100b-44d3-bf29-ccf3bd714df2 (last visited 12 January 2014)

http://yle.fi/uutiset/laakkeiden_saanti_apteekkeihin_kangertelee_kipulaakkeita_loppunut_tukusta/6767044?ref=leiki-uu (last visited 10 January 2014)

IV. Other Sources

Enemark, Ulrika, Moeller Pedersen Kjeld & Soerensen Jan, *The economic impact of parallel import of pharmaceuticals.* University of Southern Denmark Centre for Applied Health Services Research and Technology Assessment (2006) Reproduced online at http://www.reducedrugprices.org/av.asp?na=220, (last visited on 16 April 2014)

Ganslandt, Mattias and Maskus, Keith E.: *Wholesale Price Discrimination and Parallel Imports*, CESifo Working Paper No. 1951, (2007) Reproduced online at http://www.cesifo-group.de/pls/guestci/download/CESifo%20Working%20Papers%202007/CESifo%20Working%20Papers%20March%202007/cesifo1_wp1951.pdf, (last visited on 16 April 2014)

Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry & Gemmill, Marin, *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis*, LSE Health and Social Care Special Research Paper (2004). Reproduced online at - http://archives.who.int/prioritymeds/report/append/829paper.pdf, (last visited on 03 May 2014)

Danzon, Patricia M. & Epstein, Andrew J., *Effects of Regulation on Drug Launch and Pricing in Interdependent Markets*, National Bureau of Economic Research Working Paper 14041, (2008). Reproduced online at http://www.nber.org/papers/w14041.pdf?new_window=1 , (last visited on 11 May 2014).

Kyle, Margaret, *Strategic Responses to Parallel Trade*, NBER Working Paper; Reproduced online at http://www.nber.org/papers/w12968.pdf?new_window=1, 2007(last visited on 15 April 2014)

Valliluoto, Sari, Lääkehuollosta lääkemarkkinoihin – Arvoketju ja Sääntely, Kilpailuviraston Selvityksiä 2/12 Reproduced online at http://www.kilpailuvirasto.fi/tiedostot/Selvityksia-2-2012-Laakemarkkinat.pdf, (last visited 10 May 2014)

West, Peter, Mahon, James: *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May 2003, Reproduced online at http://archives.who.int/prioritymeds/report/append/8210ParallelTradeReport.pdf, (last visited 27 April 2014)

The European Commission Press Release No. IP/08/662, 30 April 2008, "Public-Research Initiative to boost the competitiveness of Europe's pharmaceutical industry"

V. Legislative Acts

Treaty on European Union (TEU), 1993

The Treaty on the Functioning of the European Union (TFEU), Consolidated Version 26 October 2012, OJ C-326/01

First Council Directive 89/104/EC of 21 December 1988 to approximate the laws of the Member States relating to trade marks [1989] OJ L 159/60, now enacted as Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trade marks (Codified version), [2008] OJ L 299/25

Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8

Council Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27, amending Directive 2001/83 on the Community code relating to medicinal products for human use, [2004] O.J. L136/34

EU Commission Guidelines on the Application of Article 81(3) of the EC Treaty (now 101(3) TFEU) of 27 April 2004, OJ C/101

Commission Notice on the definition of the relevant market for the purposes of Community competition law [1997] OJ C372/5

European Commission Communication on parallel import of proprietary medicinal products for which marketing authorizations have already been granted", COM (2003) 839 final, 30 December 2003

Communication from the Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, COM (2009) 0351 final

VI. Case law

EU Courts

Joined Cases 56/64 and 58/64, Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v. Commission, [1966] ECR 299 **(Consten and Grundig**)

Case C-24/67, Parke Davis and Co. v Probel, [1968] ECR 55 **(Parke Davis)**

Case C-78/70 Deutsche Grammophon GeschellschaftmbH v. Metro-SB-Grossmärkte GmBH&Co.KG [1971] ECR 487, **(Deutsche Grammophon)**

Case C-6/72 Europemballage Corporation and Continental Can Company Inc. v Commission, ECR 215 **(Continental Can)**

Case C-15/74 Centrafarm BV et Adriaan de Peijper v. Sterling Drug Inc. [1974] ECR 1147 **(Centrafarm v Sterling Drug)**

Case C-16/74 Centrafarm BV et Adriaan de Peijper v. Winthrop BV [1974] ECR 1183 **(Centrafarm v Winthorp)**

Case C-3/78, Centrafarm BV v. American Home Products Corp., [1979] ECR 1823 **(Centrafarm v American Home Products)**

Case 104/75, Adriaan de Peijper, managing Director of Centrafarm BV, [1976] ECR 613 **(De**

Peijper)

Case C-102/77, Hoffman- La Roche et Co v. Centrafarm Vertriebsgesellschaft Pharmaceuticher Erzeugnisse MBH [1978] ECR 1193, **(Hoffman- La Roche)**

Case C-19/77 Miller International Schallplaten v. Commission, [1978] ECR 131 **(Miller)**

Joined Cases C-32/78, 36/78 to 82/78, BMW Belgium and Others v. Commission, [1979] ECR 2435 **(BMW)**

Case C-258/78, L.C. Nungesser and Kurt Eisele v Commission, [1982] ECR 2015 **(Maize Seeds)**

Case 238/82, Duphar BV and others v. The Netherlands, [1984] ECR 523 **(Duphar)**

Case 282/82 Roussel Laboratoria BV and others v. The Netherlands [1983] ECR 3849 **(Roussel)**

Case 56/87, Commission v. Italy, [1988] ECR 2919 **(Commission v Italy)**

Case C-238/87, Volvo AB v. Erik Veng Ltd [1988] ECR 6211 **(Volvo)**

Case C-277/87 Sandoz prodotti farmaceutici SpA v. Commission of the European Communities, [1990] ECR I-45 **(Sandoz)**

Case C-249/88, Commission v. Belgium, [1991] ECR I-1275 **(Commission v Belgium)**

Joined Cases C-241-242/91P, Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission [1995] ECR I-743 **(Magill)**

Joined Cases C-267/95 and C-268/95 Merck & Co. Inc., Merck Sharp et Dohme Ltd and Merck Sharp Dohme Int. Services BV v. Primecrown Ltd et al. [1996] ECR I-6285 **(Merck v Primecrown)**

Case T-168/01 GlaxoSmithKline Services v. Commission, Judgment of the Court of First Instance,

[2006] ECR II 2969 **(CFI in Glaxo)**

Case C-418/01, IMS Health GmbH & Co. v NDC Health GmbH & Co., [2004] ECR I-5039 **(IMS)**

Joined cases C-2/01 P and C-3/01 P Bundesverband der Arzneimittel-Importeure eV and Commission of the European Communities v. Bayer AG [2004] ECR I-23 **(Bayer)**

Case C-53/03 Synetairismos Farmakopoion Aitolias & Akarnanias and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE [2005] ECR I-4609 **(Syfait)**

Case C-551/03, General Motors BV v. Commission, [2006] ECR I-3173 **(General Motors)**

Joined cases C-468/06 – C478/06 Sot. Lélos Kai Sia EE and others v. GlaxoSmithKline AEVE Pharmadeftikon Proionton [2008] ECR I-7139 **(Sot Lelos)**

Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P GlaxoSmithKline v. Commission GlaxoSmithKline Services Unlimited v. Commission of the European Communities [2009] E.C.R. I-9291 **(Glaxo)**

Case C-457/10, AstraZeneca v. Commission, 4 C.M.L.R [2013] **(AstraZeneca)**

Advocate General Opinions

Advocate General Fennelly in Joined Cases C-267/95 and C-268/95, Merck v. Primecrown, [1996] ECR I-6285

Advocate General Jacobs in Case C-53/03 Synetairismos Farmakopoion Aitolias & Akarnanias and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE [2005] ECR I-4609

United States

Abbott Labs. & Geneva Pharm., Inc., FTC Docket Nos. C-3945, 3946 (May 22, 2000)

Baxter Int’l, Inc. & Wyeth, FTC Docket No. C-4068 (Feb. 3, 2003)

Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp., 266 F. 71 (2d Cir. 1920)

Glaxo Wellcome plc & SmithKline Beecham plc, FTC Docket No. C-3990 (Jan.26, 2001)

Hoechst Marion Roussel, Inc. & Andrx Corp., FTC Docket No. 9293 (Mar. 16, 2000)

Jazz Camera Photo v. Int’l Trade Comm’n, 264 F.3d 1094 (Fed. Cir. 2001)

Schering-Plough Corp., Upsher-Smith Labs. & Am. Home Prods. Corp., FTC Docket No. 9297 (Mar. 30, 2001)

United States v. Grinnell Corp, 384 U.S. 563, 570-571 (1966)

Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, 124 S. Ct. 872 (2004), *rev’g* 305 F.3d 89 (2d Cir. 2002).

Annex I

Questionnaire to DG Competition Mr Borja Castromil, answers received by phone on 18 February 2014 and 14 April 2014

Specific features of the pharmaceutical sector

Q1. Should the pharmaceutical sector be treated differently in regard to competition law due to its specific characteristics?

A1. *The Commission's approach to that question can be found in the case law, such as GSK v. Commission; Syfait and Sot Lelos. The Commission respects the outcome of the Court decisions. We acknowledge that the pharmaceutical industry is a specific area, still the competition law has to apply also to that sector.*

Dual pricing in pharmaceuticals

Q2. In the case of GlaxoSmithKline, the Court of Justice upheld the General Court's finding that dual pricing may in principle benefit from an exemption under art.101(3), if its efficiencies outweigh its anti-competitive effects. Is the EU Commission considering further regulatory measures in order to define the right balance between these efficiencies and anti-competitive acts?

A2. *This issue is open at the moment. We acknowledge that there is uncertainty with dual pricing practices and some questions raised in Glaxo are still open and it is true that the Commission has to do something about the uncertainties (Glaxo case) at some point. Commission will take into account the decision of the court, especially regarding the possible exemption under Article 101(3) TFEU, but as it was not an order, the Commission has not published any further documents or statements so there is no development so far. However, there are now two cases in Spanish Supreme Court, regarding dual pricing practices. Pfizer and other major pharmaceutical manufacturers are involved in those cases. The decision was to be given last year, but the Supreme has not decided yet. However, the Commission hopes that the decision will be given this year since it would be an important decision for the Commission also.*

The new probe on parallel trade

Q3. According to Bloomberg news article, the Commission has started a probe/questionnaire on parallel trade of medicines (already in 2012), do you know what would be the situation with that?

A3. *After the Glaxo case, in March/April 2012, the Commission performed an inquiry to the Spanish wholesalers, which was a formal request for information under Article 18 of the Commission regulation 1/2003. However, that was not a pharmaceutical sector study as in 2009 about the generic medicines. We have got the replies from the wholesalers, but nothing has been published by the Commission about the study and there is no new development after the study.*

Harmonization of drug prices

Q4. Are there any discussions or framework ongoing regarding harmonization of prices on EU level? What kind of challenges do you see in harmonization from competition point of view?

A4. *There are no current initiatives of price harmonization in DG Competition and the Commission has no opinion of this at the moment. If there would be any initiatives, it would involve also other service areas, such as DG Health and Services and DG Enterprise, since this is more related to internal market issues. The DG Competition has had meetings with the industry, where there have been discussions about the current pricing policies of pharmaceuticals. There are several opinions about how the pricing policy should be. However, there are no guidelines or no initiative about the subject by the Commission.*

Shortage of prescription medicines

Q5. The UK Government's All-Party Pharmacy Group (APPG) has called upon the country's Department of Health to propose legislation to prevent exports of prescription medicines from the UK with the aim of protecting national public health due to the shortages of prescription medicines. Also the APPG has issued a joint call for action to Governments, EU regulators and the Commission to tackle the issues of shortages.[233] How does the EU Commission react on this kind of initiative and joint call raised by APPG? Could a Member State ban parallel imports/exports and on which grounds?

A5. *We are not aware of those issues, so there is no opinion of the DG Competition. The issue of supply shortages is one of greater discussion. Shortages may come from different causes. The issue of a Member State banning parallel imports/exports is not a question competition law as such, so the DG Competition has no opinion of this. The issue of supply is under the competence of DG Health and Consumers, based on Article 81 of the Directive 2001/83.*

[233] The representative organizations for European community, hospital and industrial pharmacists have issued a joint call for action by Governments, regulators and the European Commission to tackle the growing problem of medicines shortages (Joint Press Release 16 May 2013).

Current issues of pharmaceutical parallel trade

Q6. What are the current issues in regard to parallel trade of pharmaceuticals?

A6. *The Commission has no official view on this, so this is a personal opinion. However, the things that are interesting at the moment would be the following:*

- Due to the economic crisis in Europe, the situation of the pharmaceutical industry has got more difficult in terms of parallel trade, but of course the outcome of this will depend on the general market situation so the Commission will follow this development.

- International reference pricing and how it affects to parallel trade.

Annex II

Questionnaire to FCCA, the Finnish Competition and Consumer Authority, Mr Jan Nybondas, answers received by email on 11 November 2013

Q1. Is there any difference of opinions between the Commission of the European Union and the Finnish Competition and Consumer Authority concerning parallel imports or exports of pharmaceuticals and what kind, if any?

A1. No, there is no difference of opinions in this matter.

Q2. Do pharmaceutical markets have a special characteristic in parallel importation? If they do, how is this special feature supported?

A2. Country specific price regulation and reimbursement systems of medicines in the EU Member States have an impact on the access of a parallel imported product into a country's market.

Q3. What is FCCA's opinion on the harmonization of pharmaceutical prices at EU/ETA level?

A3. Price harmonization would be by nature a political decision, and highly complex, for example, due to different buying power of the citizens. Thus, harmonization remains to be resolved by policy-makers. The Finnish Competition and Consumer Authority does not have a standpoint in this matter.

Q4. Has FCCA been asked to give its opinion on restriction of parallel imports (or exports) of pharmaceuticals and its consequences from competition law point of view?

A4. The Finnish Competition Authority, FCA, (now: Competition and Consumer Authority, FCCA) has stated in April 2012 in its initiative to the Finnish Medicine Agency, Fimea, that it thinks the access of parallel imported medicines into markets is being hindered without justification. The main problems are weak realization of offering of the most inexpensive inter-changeable medicine and non-inclusion of a parallel imported medicine in the same reference price group together with the original medicinal preparation in case the preparation has not been released for generic manufacturing.[234]

[234] http://www.kilpailuvirasto.fi/cgi-bin/english.cgi?luku=news-archive&sivu=news/n-2012-04-10

To be more precise, FCA stated in its initiative that Fimea should take measures to ensure that substitution of medicines would support a full-scale price competition prescribed by the Medicines Act. In order to meet this target, there should be a monitoring system showing in real time that the cheapest interchangeable medicines are those which are primarily ordered, stored and delivered.

Furthermore, FCA proposed in its initiative that legislation regarding the priority of the most inexpensive interchangeable medicines in the pharmacies' drug sales should be clarified. In FCA's opinion, also the earnings logic of pharmacies should be changed so that they would have a stimulus to offer even the most inexpensive medicine to the clients. In addition to the statements above, FCA found that inclusion of parallel imported pharmaceuticals into the reference price system in its full extent should be reconsidered.

Q5. How much has the parallel importation of pharmaceuticals increased competition and decreased prices of prescription and non-prescription drugs sold in Finland after parallel imports became permitted? Would there be any statistics on the impact?

A5. Referring to the previous answer and based on reasons explained earlier, market share of parallel imports is very low (1-2 %) and has not increased to the level of many other EU Member States. Thus, the effect of parallel imports of medicines on the retail prices of pharmacies is insignificant. Parallel imported medicines have been slightly more attractive in tenders announced by hospital districts where agreements are made for longer periods. For further information, we advise to turn to the Pharmaceuticals Pricing Board, Hila.

A5. Hila's answer: There is no statistics on the effects of parallel trade on prices or competition in Finland. An empirical study on generic medicines was recently made by the Eastern Finland University together with the Social Insurance Institution of Finland.

Q6. Has there been any shortage of (prescription) drugs? In case of shortage, does FCCA see any causal relation between it and increased parallel trade (parallel exports)?

A6. This question should be brought up to the pharmaceutical authorities. According to our knowledge, there haven't been any drug shortages because of parallel imports or exports.

A6. Fimea´s answer: In general, we may answer that generic substitution and the reference price system have, perhaps more that parallel imports, impacted on the availability of pharmaceuticals.

A6. Hila's answer: No, practically there haven't been any shortages. The availability is 99%.

Q7. According to FCCA, is there any threat that parallel importation of medicines would jeopardize national research and development and innovations of drugs?

A7. In our opinion, this kind of threat caused by parallel importing of medicines does not exist. However, it is obvious that parallel imported products, when causing a strong price competition create a more challenging business environment for the manufacturers of the original products. In that case, assets available for research and development will decline unless new breakthroughs in R&D take place, enabling to increase amount of manufactured products protected by patents.

Q8. How can FCCA influence on finding a balance between EU competition law and IPRs for in regard to parallel importation of pharmaceuticals?

A8. In the EU, this balance is primarily being searched so that the European Commission takes to European Court of Justice such disputes which have arisen after a drug manufacturer has through special arrangements tried to restrict deliveries to a Member State in order to affect the amount of parallel trade. The Finnish Competition and Consumer Authority is given opportunity to express its view in the Commission's consultative meetings to matters concerning parallel importation and try to influence on the Commission's resolution in case it considers it necessary.