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Parallel Trade Restraints in Pharmaceuticals and EU Competition Rules

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Abstract: The European Union protects parallel trade as one of the foundations of the Union. Although the pharmaceutical sector is more sensitive to parallel trade, no distinction is made for this specific industry. Thus, this thesis tries to cover parallel trade issues in pharmaceutical industry and assess whether there is room for justified restrictions of parallel trade within EU competition rules.

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SUMMARY

Recent studies show that the EU pharmaceutical sector is losing competitiveness in comparison with the US sector. This has incited debates about adverse side effects of parallel trade on future R&D.

In this regard, this thesis tries to examine the possible justifications of restrictions on parallel trade in the frame of EU competition rules. The thesis starts with the description of parallel trade itself and compares two jurisdictions, namely the EU and the US with respect to parallel trade in pharmaceuticals. This comparison shows different policy goals the EU is faced with, which motivates the legality of parallel trade and directs the CJEU to protect it in order to achieve the market integration.

The subsequent chapter analyzes important case-law of the pharmaceutical sector concerning restrictions on parallel trade within the EU competition rules. It discusses the emergence of a new trend while assessing the legality of restrictions on parallel trade; by looking at R&D, consumer well-fare arguments, as well as the specificity of pharmaceutical industry based on price control through state intervention.

The final chapter discusses pros and cons of parallel trade from an economic perspective; this helps to consider how pharmaceutical companies can use these arguments to justify restriction on parallel trade in light of the EU Court's case-law, taking into consideration the trend suggested by the EU Courts, and fit them in Articles 101 and 102 TFEU.

Finally, a conclusion is drawn, that the EU Courts are cautious to accept different treatment of the pharmaceutical sector. However, it is suggested that the EU Courts would open doors for the justification of restrictions on parallel trade, but only if a direct link between parallel trade and loss in long-run dynamic efficiency is proven by a pharmaceutical company. Furthermore, this will be done only on a case by case basis in order to not sacrifice the goal of achieving an internal market, where the competition rules play an important role. In the light of this conclusion, pharmaceutical companies when thinking of minimizing the risks of competition concerns are advised to consider the important trends and aspects of EU case-law.

PREFACE

This thesis marks the end of my studies in European Business Law at the Law Faculty of Lund University. The programme has given me a deeper understanding of European Union Law.

Looking back two years, I was only hoping to get accepted in this programme but now I can proudly say that I have grown and learned a lot.

Thus, I would like to use this opportunity and express my gratitude to all the people who have supported me during my studies.

I want to thank everybody and mostly Swedish Institute for giving me this opportunity.

I also wish to thank Xavier Groussot, an excellent professor of EU Constitutional Law whose comments and advices throughout my stay at the department, especially during the moot court sessions, shaped me in EU Law. I would also like to mention that the time spent, working with my colleagues and coaches for the moot court, is unforgettable.

I am extremely grateful to my supervisor, Professor Hans-Henrik Lidgard for patience, advice and guidance during my thesis writing. He has helped me to formulate and structure the research problem of this thesis.

Thank you and I hope the readers enjoy this work.

ABBREVIATIONS

AG	Advocate General
GC	The General Court of the European Union
CJEU	The Court of Justice of the European Union
EAEPC	European Association of Euro-Pharmaceutical Companies
EAGCP	Economic Advisory Group on Competition Policy
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Evaluation Agency
FDA	Food and Drug Administration in the US
IP	Intellectual Property
IPR	Intellectual Property Right
OECD	Organisation for Economic Cooperation and Development
R&D	Research and Development
TEU	Treaty on European Union
TFEU	Treaty of Functioning of the European Union
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WTO	World Trade Organization

1. INTRODUCTION

There are ongoing debates about pros and cons of parallel trade in the pharmaceutical sector, among both economists and lawyers. Consequently, there are different approaches to this issue across the world.

In the European Union (EU) parallel trade is not only allowed but rather is promoted and protected, since it serves the aim of achieving a single internal market based on the principle of free movement of goods. Contrary, in the United States (US), parallel trade of pharmaceuticals is prohibited, since the integration is not a market goal of the US, as it follows federalist structure. Parallel trade is not always a profitable thing, especially for pharma industry. Thus, in order to eliminate parallel trade, pharmaceutical companies tend to adopt different practices such as dual pricing, refusal to supply, quotas, export bans, etc.

In the EU a regional exhaustion of Intellectual Property Rights (IPRs) ensures the legality of parallel trade and the CJEU protects it by virtue of competition rules for the proper functioning of the internal market.

Thus, this thesis addresses these issues, i.e. whether parallel trade by pharmaceutical companies can be justified in the ambit of EU competition rules. The possible justification of restraints on parallel trade lies in the triangle of competition law, Intellectual Property (IP) protection and EU integration. Hence, the problem of achieving a balance among them during the enforcement of competition rules is recognized as an underlying thought throughout the thesis.

1.1. Purpose

This thesis aims to examine whether the restrictions of parallel trade by pharmaceutical companies can be accommodated within the ambit of EU competition rules.

The questions below paves way to the research subject and serves as an auxiliary to the core question: What is parallel trade as such? What is the legal stand of parallel trade in two different systems? What are the incentive factors of parallel trade in pharmaceutical industry and the adverse impact on Research and Development (R&D)? What is the European Courts and Advocate Generals' (AGs) position concerning the parallel trade restrictions by pharmaceutical companies? What are pros and cons of parallel trade in the light of short term economic

efficiency and long-run consumer welfare? And, how can pharmaceutical companies defend the restrictions on parallel trade under the EU competition rules?

1.2. Method and Material

In order to achieve the purpose of this paper traditional legal method and comparative method are employed.

Traditional legal method involves primarily the review of case-law, with focus on case-law of the Court of Justice of the European Union (CJEU); the commentary of judgments by the General Court (GC) and the CJEU is supplemented with opinions of AGs, in order to analyze existing situations in the researched field and detect future possible developments. The thesis does not analyze deeply the classical sources such as European primary and secondary legal texts, but rather touches upon them when necessary.

Comparative analysis between the US and the EU system are conducted in order to understand the rationale of different approaches adopted by two jurisdictions. Conclusions are drawn bearing in mind crucial differences and significant departures of the two jurisdictions.

Economic perspective plays an important role in whole discussion, and hence, economic considerations are touched upon as an influential factor in the decision making at legal level. Specifically, it is assessed and decided whether the EU Courts consider economic factors while dealing with the restriction of parallel trade of pharmaceuticals as an anticompetitive action.

In addition much data of non-legal nature is also provided to accurately describe all relevant aspects of the pharmaceuticals market in an attempt to cover the area as comprehensively as possible. Due regard will be given to the reports and researches done by European Federation of Pharmaceutical Industries and Associations (EFPIA) in various studies, which will provide much of the background information.

1.3. Delimitations

This thesis is written bearing in mind an assumption, that the readers possess basic knowledge of EU law and EU competition law principles.

The thesis aims to discuss parallel trade from EU competition law perspective, however, does not go into depth of doctrines around Article 102 TFEU, such as refusal to license or essential facility doctrines and the relevant case-law. Articles 101 and 102 TFEU are discussed only with respect to parallel trade cases in pharmaceutical field.

The thesis provides some comparative analysis in light of the US system, as a support to understand the rationale for allowing parallel trade in Europe. Thus, comparison will be mainly restricted to only with the legal status and influential factors of parallel trade in the US.

Since the concentration on IP law is not the purpose of this thesis, the background to IP law is not provided. Rather, IPRs are only referred and considered as far as it concerns the balance between the risks and rewards of innovation.

Free movement of goods and the achievement of an internal market as an aim of the EU are dealt as far as it concerns parallel trade; however the detailed analysis on this issue is not conducted.

As one could think, the discussion on parallel trade almost always brings generics in to the topic; however, a delimiting line should be drawn here and said that generics fall outside the scope of this thesis. In addition, the issue and legality of repackaging of pharmaceuticals and the trade mark law are also not discussed.

2. PARALLEL TRADE

2.1. Parallel trade in general and exhaustion of IPRs

Parallel trade is a resale of goods between countries without the authorization of the owner of the IPRs connected to those goods.¹ However, parallel trade does not include unofficial or illegal, activities that may take place inside a country or among countries. Furthermore, it is not a trade in pirated or counterfeit products. Parallel imports are genuine products that do not violate IP rights.²

The cause of parallel trade is price discrimination, 'whereby an identical product is sold at different prices in different countries'.³

From a legal perspective parallel trade raises question such as to what extent should countries allow or restrict the ability of IPRs holders to control the movement of products across different markets on the basis of local ownership of IPRs.⁴

Indeed, parallel imports have been admitted in many countries on a regional or international scale.⁵ The TRIPS Agreement itself, gives the World Trade Organization (WTO) members the freedom to design their own regimes of IPR exhaustion.⁶

There exist three types of exhaustion all over the world. *National exhaustion*: exclusive rights of IPR holders cease after the first sale of the product within national borders. According to this type of exhaustion IPR holders can stop parallel imports from entering the local market, even though their rights are exhausted in that market. This may for example be seen in the US.⁷

Regional exhaustion operates in the same way as national exhaustion. It has consequences in the territories of several countries that form a trade region.⁸ This means that parallel trade is

¹ Margaret K. Kyle, 'Parallel Trade in Pharmaceuticals: firm response and Competition Policy' in Barry Hawk (ed), *International Antitrust Law & Policy: Fordham Competition Law 2009* (Juris Publishing 2010), ch 13, 339.

² Duncan Matthews and Viviana Munoz-Tellez, 'Parallel Trade: A User's Guide' in A Krattiger and other (eds), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A.), Ch 15.4,1429, <<http://www.iphandbook.org/handbook/ch15/p04/>> accessed 5 April 2013.

³ Kyle (n 1) 339.

⁴ Matthews and Viviana Munoz-Tellez (n 2) 1432.

⁵ Carlos Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries (South Centre: Geneva,2000), 74,<<http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf>>, accessed 5 April 2013.

⁶ The Agreements on Trade Related-Related Aspects of Intellectual Property Rights, signed in Marakesh, Morocco on April 15th 1994, Article 6.

⁷ Matthews and Viviana Munoz-Tellez (n 2) 1432.

⁸ WIPO Secretariat, 'Interface Between Exhaustion of Intellectual Property Rights and Competition Law', CDIP/4/4 REV./STUDY/INF/2, June 12011, 5.

allowed within the region, however right holders can ban the import from the countries outside the region, and the perfect example of such a regime is the EU.

Finally there is an *International exhaustion*, where IPR holders' rights over products cease after the first sale in any market. Thus, IPR holders cannot block parallel imports from entering the local market. This system is adopted by Kenya.⁹

2.2. Parallel trade in Europe as a means for integration

In order to achieve the establishment of a single European market any quantitative restrictions or measures having equivalent effect are prohibited by virtue of Article 34 TFEU and following the seminal case *Cassis de Dijon*.¹⁰ Thus, conflict between exercise of IPRs and free movement of goods has been resolved on the basis of the principle of regional exhaustion of IPRs. The principle of regional exhaustion derives from Articles 34 and 36 TFEU, as well the case *Deutsche Grammophon/Metro*.¹¹ In this case a German undertaking, owner of a copyright, used its exclusive right of distribution to prohibit the import of sound recordings from France to Germany.

The CJEU stated that while the existence of an IPR is protected, the exercise of an IPR may violate the rules enshrined in the Treaty. Particularly, when such exercise runs against the free movement of goods, justification should be considered on the basis of the grounds contained in Article 36 TFEU. This article, being an exception to the paradigm of free movement, should apply as long as this derogation is indispensable to protect the rights.

This paved the way to legality of parallel trade in the EU. Protection of parallel trade is evident in the early case-law for example in *Hoffmann-La Roche*.¹² The CJEU ruled that a trade mark owner may not prevent a parallel importer from repackaging a good if this is necessary for him to be able to sell it in another Member State.

⁹ Matthews and Viviana Munoz-Tellez (n 2) 1432.

¹⁰ Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649.

¹¹ Case 78/70 *Deutsche Grammophon GmbH v. Metro-SB-Großmärkte GmbH & Co. KG* [1971] ECR 487.

¹² Case 102/77 *Hoffmann-La Roche & Co. AG v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH* [1978] ECR 1139.

This approach is now supported by the secondary legislation such as the Trade Mark Directive¹³, particularly Article 7, which enshrines the principle of ‘exhaustion of rights’ at an European Economic Area (EEA)-wide level. Moreover, the CJEU made it clear that Member States are no longer free to opt for an international exhaustion.¹⁴

In the light of the foregoing, parallel trade is absolutely legal in the EU. Furthermore, it constitutes ‘a central facet of the integration of European economies and is strongly encouraged by the European Institutions.’¹⁵

2.3. Comments and transition

Even though parallel trade is now at an advanced stage in Europe, there still remains the question of its absolute protection in pharmaceutical sector. While parallel trade is accepted as a means for integration which upholds the foundation of the EU and serves the aim of a single Union market, it is not necessarily beneficial to all industries. Thus, the possibility for the pharmaceutical companies to justify the restraints on parallel trade in the triangle of integration through parallel trade, competition and IP laws is not straightforward.

Above descriptive section paves the way to discuss and compare parallel trade in pharmaceuticals in two different jurisdictions the EU and the US which recognize respectfully, regional and national exhaustion of IPRs. This comparison serves the aim of understanding the rationale behind the different approach and why the US system will not work in the EU.

In addition, during the comparison, the specific nature of pharmaceutical market is taken into consideration, which makes this industry sensible to parallel trade and hence, requires more cautious approach.

¹³ Directive 2008/95/EC of 22 October 2008 to approximate the laws of the Member States relating to trade marks [2008] OJ L299/25.

¹⁴ See Case C-355/96 *Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH* [1998] ECR I-4799 with respect Trademark directive, paras 22-27.

¹⁵ Melanie Farquharson and Vincent Smith, *Parallel Trade in Europe* (Sweet & Maxwell 1998).

3. PARALLEL TRADE IN PHARMACEUTICALS IN EUROPE AND THE US

3.1. Single pharmaceutical market in the EU

In order to assess the intersection of competition and IP laws for the purposes of parallel trade a good understanding of the way pharmaceutical sector functions is needed. To this end, this section commences with an overview of functioning of the pharmaceutical market in the EU.

In order to ensure the consumer protection, clinical tests and a prior authorization systems are required before any products could be lawfully marketed, making this industry one of the most regulated both in the EU and at the National Level. Each Member State had their own marketing and approval authorization for pharmaceuticals, which created obstacles to free movement of drugs in the Union.

The first steps to remove these obstacles and create one system were adoption of a few Directives¹⁶ that introduced a procedure for the mutual recognition of national marketing authorizations in different Member States. Finally, ‘the Commission outlined an industrial policy program that led to the creation of the European Medicines Evaluation Agency (EMA) and to the establishment of new harmonized procedures to obtain a marketing authorization.’¹⁷ EMA’s mission statement is “to promote the protection of human health... and of consumers of medicinal products”.¹⁸ This goal is to be achieved through a greater level of harmonization of pharmaceutical regulation within the EU. Hence, now, there are three different procedures to obtain a marketing authorization for pharmaceutical products:¹⁹ a) The National Procedure, b) The Mutual Recognition and Decentralized Procedure, c) The Centralized Procedure.

¹⁶ Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1965] OJ 369/65; Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal product [1975] OJ L147/1; Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1975] OJ L147/13.

¹⁷ Claudia Desogus, ‘Competition and Innovation in the EU Regulation of Pharmaceuticals: The case of parallel Trade,’³⁹ <<http://repub.eur.nl/res/pub/19408/Proefschrift%20Claudia%20Desogus.pdf>>accessed 6 April 2013.

¹⁸ See Council Regulation (EC) 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of Medicinal Products [1993] OJ L214.

¹⁹ Desogus (n17) 39.

The third procedure serves the aim of single pharmaceutical market and facilitates free movement of pharmaceuticals all over the EU; as it is centralized and entirely managed by EMEA. It allows companies to have a unique authorization valid within the whole territory of the EU.

3.1.1. Fragmentation of the market through price differences

Although progress has been made in the past years in harmonization of the pharmaceutical markets, the pricing decisions have continued to be operated on a national basis, which results in price differences across the Member States.²⁰ A single pharmaceutical market process has been distracted by the considerable fragmentation of the national markets with different pricing regulations and reimbursements.²¹

Price difference across the countries in the EU is caused on one hand by the national price control mechanism and on the other hand by the pharmaceutical companies, pricing their products according to the ability of the consumer to pay in the particular market, aiming to obtain the highest price each market can bear. This creates price differences among the Member States, which is the result of an interplay between private and public interests. The way in which this balance is struck between opposing interests varies from country to country, depending on the health care system, on the industrial policy pursued, reimbursement policy etc.,²² as well, on the health status of the citizens, on medical culture etc.²³

In addition almost all EU countries except Germany and the UK apply direct price controls to on-patent drugs.²⁴

Traditionally, Northern European countries, counting on higher income per capita, always opted for health care policies allowing for free pricing of medicinal specialties, in order to promote the growth of in-house pharmaceutical industry; contrary, in Southern European

²⁰ Aysegul Timur and Gabriel Picone, 'Regulating The Pharmaceutical Industry in the European Union: A Dilema of Achieving of Single Market', (International Business & Economics Research Journal - July 2010) Volume 9, Number 7, 29. < <http://journals.cluteonline.com/index.php/IBER/Article/view/595/581> > accessed 9 April 2013.

²¹ Ibid 30.

²² Desogus (n 17)41.

²³ See in this regard: Stuart O. Sschweitzer, *Pharmaceutical Economics and Policy* (Oxford University press 2007).

²⁴ Timur and Picone (n 20) 30. Direct price controls include negotiated prices, price-caps (fixed maximum price), cost-plus prices, price comparison etc.

countries, with lower income per capita, aimed at directly monitoring prices of medicines, in order to keep health care expenses under control.²⁵

The significant price difference in pharmaceutical industry across the EU creates the fragmentation of the market. Therefore according to some commentators it is impossible to speak of a single market for pharmaceuticals.²⁶ Many times the CJEU²⁷ and the European Parliament²⁸ called on the Commission and the Council to remedy distortions caused from price differentials. However, drugs pricing and related decisions are still under exclusive national competence.²⁹

The national price control not only results in fragmentation of the pharmaceutical market but as well facilitates the parallel trade in the Union as a main incentive factor.

The price differences resulting from the price control creates a ground for parallel trade, which is protected by the free movement principle. Whether price control itself is a measure equivalent to quantitative restrictions will be briefly examined below.

Following *Roussel*³⁰, the price control as such is not contrary to free movement of goods, as long as it is not applied in a discriminatory manner. Although negative attitude towards discriminatory measures is not absolute, in *Decker*³¹ the CJEU stated that even the rule of prior authorization encouraged buying products in Luxemburg rather in other Member State and was discriminatory; it could have been justified by the risk of seriously undermining the financial balance of social security system.

²⁵ See: Panos Kanavos, 'Overview of pharmaceutical pricing and reimbursement regulation in Europe', 13–19, <http://www.eco.uc3m.es/servicios/sesam/actividades/jornada_legislacion/DOC%209%20EMEARoadMap.pdf> accessed 5 April 2013.

²⁶ Mellanle and Smith, (n 15) 68, affirming that the pharmaceutical industry is a 'sector where the creation of a single European market is highly unlikely to occur even in the medium to long term due to the interest of national governments in controlling spending on pharmaceuticals.'

²⁷ See Case 15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc* [1974] ECR 114, para. 23.

²⁸ See the EU Parliament's Resolution on the Communication from the Commission on the Single Market in Pharmaceuticals [1999] OJ C279/79.

²⁹ See the Commission, 'Communication on Single Market in Pharmaceuticals' COM(98)588 final, p. 7-8, 12, 18, where the Commission affirms that these matters are mostly within the exclusive competence of the Member States and, pursuant to the principle of subsidiarity, should be left to national authorities; See as well 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 organization 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.*

³⁰ Case 181/82 *Roussel Laboratoria BV and others v État néerlandais* [1983] ECR 3849.

³¹ Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés* [1998] ECR 1831, para 36, 39.

It is clear from the line of the case-law that differences between national health care systems are not considered as obstacles to the free movement of goods.³²

In conclusion, the price control in Member States creates the fragmentation of the pharmaceutical market; however they are not measures hindering free movement of goods. Moreover, it creates the situation which facilitates the parallel trade and by protecting parallel trade the EU achieves the aim of an internal market. Before, turning to parallel trade in pharmaceuticals in the EU and the US precisely, some overview of pharmaceutical sector in the EU with some comparison with the US industry focused on figures will be touched upon below.

3.2. EU pharmaceutical industry in figures

The pharmaceutical industry in terms of production, revenue generation and employment is one of the best-performing high-technology industries in Europe.

According to the latest estimates, the pharmaceutical industry in 2011 provided about 660,000 units of employment in Europe, of which 116,000 are devoted to R&D.³³

According to the EEPIA 2012 report the research-based pharmaceutical industry can play a critical role in restoring Europe to growth. In 2011 it invested an estimated € 27,500 million in R&D in Europe and research-based pharmaceutical industry is a key asset of the European economy.³⁴

However, European pharmaceutical market is losing competitiveness in regard to its main competitor, the US.³⁵ Moreover, there is rapid growth in the market and research environment in emerging economies such as Brazil, China and India, resulting in further migration of economic and research activities outside of Europe to these fast-growing markets.³⁶

The graph below³⁷ shows that Europe compared to the US is quite behind when it comes to the investment in R&D.

³² See Panos Kanavos, 'The Single Market for Pharmaceuticals in the European Union in Light of European Court of Justice Rulings,' (*Pharmacoeconomics*2000) Volume 18, Issue 6,523-532.< <http://link.springer.com/journal/40273>> accessed 7 April 2013.

³³ See EFPIA, 'The Pharmaceutical Industry in Figures', (2012) ,< <http://www.efpia.eu/pharmaceutical-industry-figures-edition-2012>> accessed 10 April 2013.

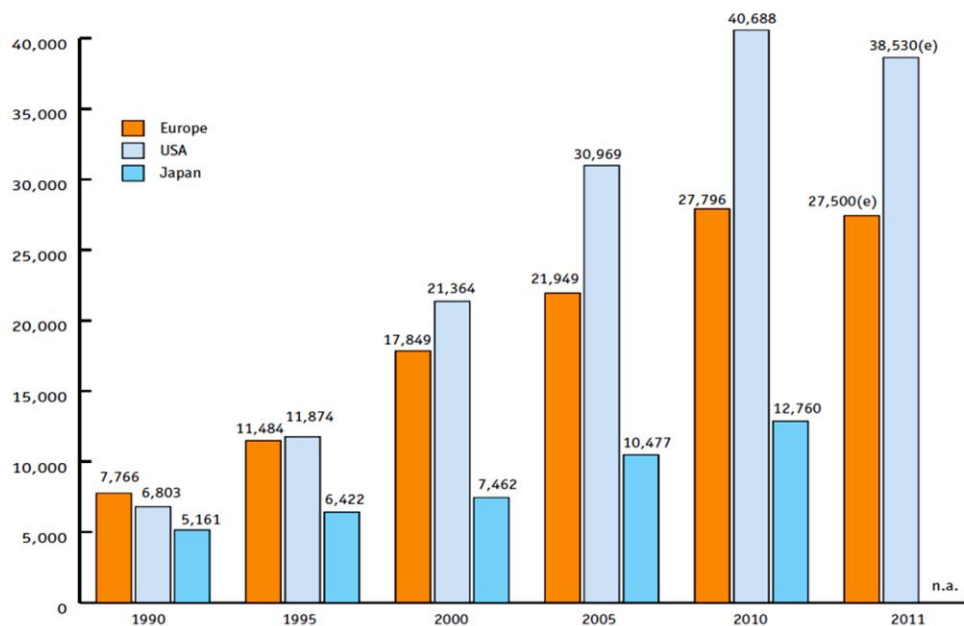
³⁴ Ibid.

³⁵ Desogus (n17)32.

³⁶ EFPIA(n 33) 9.

³⁷ EFPIA (n 33) 5.

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA AND JAPAN
(MILLION OF NATIONAL CURRENCY UNITS*), 1990-2011



*Note: Europe: € million; USA: \$ million; Japan: ¥ million x 100
(e): estimate

Source: EFPIA member associations, PhRMA, JPMA

Parallel trade was estimated to amount to € 5,100 million (value at ex-factory prices) in 2010.³⁸ It generally deprives the industry of additional resources to fund R&D. Hence, in order to maintain the competitiveness of EU pharmaceutical industry, parallel trade should be treated carefully, so as to not remove the incentive for R&D.

3.3. Parallel trade of pharmaceuticals in the EU

The Commission reaffirmed in its communication in 1998 that pharmaceuticals are fully governed by the rules for functioning of the internal market.³⁹ Later, in 2003 parallel trade was recognized as a legal form of trade among Members States.⁴⁰

³⁸ Ibid 4.

³⁹ Commission, 'Communication n on the single market in pharmaceuticals' (Communication) COM (1998) 588.

⁴⁰ See Commission, 'Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted' COM (2003) 839.

Price difference on pharmaceutical products is a main incentive of parallel trade, which results the flow of pharmaceuticals from Southern European countries such as Spain and Italy, where the prices on pharmaceutical products are relatively low compared to Northern European Countries as for Denmark, Sweden and the UK.

Parallel trading is flexible, since it includes little capital investment, parallel traders as entrepreneurs have no long term concerns for the industry. They have no R&D programmes, and they make a regular use of the Courts including the CJEU.⁴¹

In addition, parallel trade is facilitated by the centralized system of market authorization. When a directly distributed product is approved centrally by the Commission, following a positive opinion from the EMEA and in accordance with Regulation⁴², no further regulatory approval is required if the product is identical in every Member State.

However, there still could be some impediments to parallel traders such as: a linguistic compliance check on the pack labeling according to Article 76(3) of the Directive 27/2004/EC,⁴³ importers are required to notify the full marketing authorization holder and the competent authority in the Member State of destination of their intention to parallel distribute a product. In addition, under trademark law, the importer must also notify the trademark owner. These requirements can be considered as obstacles for parallel trade.

In addition to already mentioned factors, parallel trade is encouraged as well through the regional exhaustion of the IPRs in Europe and this is itself connected to the patent protection which does not allow any other competition such as generic products. Thus, the only form of competition is parallel trade during the patent lifespan.

Comments:

To sum up, the above factors can be organized in the following way: a) factors making parallel trade of pharmaceuticals legal and possible and b) factor which influences legality as well as ease parallel trade.

Regional exhaustion of IPRs is one of the aspects which make parallel trade legal while pharmaceutical product is still protected by patent. Price differences are driving factors which

⁴¹ REMIT Consultants, *Impediments to parallel trade in pharmaceuticals within the European community*, (the study was carries out under a contract with the Commission) (Luxembourg 1992),5.

⁴² Regulation 726/2004 (EC) of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1.

⁴³ Directive 27/2004/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L136/34.

incite parallel trade and promise profit to parallel traders. Centralized system of marketing authorization at EU level makes parallel trading of pharmaceuticals at the same time legal and as well easy to be conducted.

In the next section, parallel trade of pharmaceuticals in the US will be analyzed and compared with EU system.

3.4. Parallel trade of pharmaceuticals in the US

Exhaustion of IPRs is not a straightforward issue in the US, since no Court has ruled specifically on the issue of national vs. international exhaustion of IPRs.

According to Rebecca Eisenberg, ‘the US bargaining position, supported by the pharmaceutical industry, has been that every nation should follow a rule of national exhaustion. But it is not at all clear that this is the law in the US.’⁴⁴

The issue is not clear not only regarding the pharmaceuticals but concerning all industries as well. In order to understand whether the US allows parallel trade in pharmaceuticals the exhaustion of IPRs in general should be reviewed.

Exhaustion of IPRs is unclear when it comes to copyrights also. On one hand, the section 602(a) of the copyright act in the US reads:

[I]mportation into the United States, without the authority of the owner of copyright under this title, of copies or phonorecords of a work that have been acquired outside the United States is an infringement of the exclusive right to distribute copies or phonorecords.⁴⁵

But, on the other hand, in the case *Quality King Distributors, Inc. v. L’anza Research International, Inc*⁴⁶ the US Supreme Court limited the rights of copyright holders to prevent parallel trade and is consistent with international exhaustion of copyrights. This case concerned parallel trade in products first manufactured in the US and then exported. Contrary, the 9th Circuit Court of Appeals stated explicitly that the “first-sale” doctrine did not apply in *Omega*,

⁴⁴ R. Eisenberg, ‘Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development’, (Fordham Law Review 2003) volume 72, issue 33, 485 <<http://ir.lawnet.fordham.edu/flr/vol72/iss3/1/>> accessed 25 March 2013.

⁴⁵ Copyright Law of the United States: and related laws contained in title 17 of the United States Code, (2011 december), Section 602(a) <<http://www.copyright.gov/title17/circ92.pdf>> accessed 10 March 2013.

⁴⁶ *Quality King Distribs. Inc., v. L’anza Research Int’l Inc.*, 523 U.S. 135 (1998).

S.A. v. Costco Wholesale Corporation,⁴⁷ which involved importation into the US of watches manufactured in Switzerland (with the US copyright).

However, trademark owners have the right to prevent parallel trade.⁴⁸ Similarly, the patent act 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.’⁴⁹ Thus, the US patents owners can claim the infringement and through it prevent the unauthorized imports of their products.

In *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng’g Corp.*⁵⁰ the Court ruled that because the patent owner had not expressly forbidden resale into the US by its licensee, the patent owner could not prevent parallel trade. While in *Jazz Photo v. International Trade Commission*⁵¹ the Court reestablished that US patent owners could claim infringement by the import of goods legally purchased abroad, stating that ‘[T]o invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the US patent.’

In order to analyze the legal stand of parallel trade of Pharmaceuticals in the US only exhaustion rule alone would not help rather safety of importation should be considered as well. Unlike the EU market, here we are dealing with the importation from different countries which can have the different safety requirements from the US.

Thus, parallel trade in pharmaceuticals is somewhat complicated in the US by the Federal Food, Drug and Cosmetic Act and its amendments. The primary concern of this Act is safety, rather than exhaustion of IPRs and there are a number of provisions relevant to the import of pharmaceutical products. Only the US manufacturer of a pharmaceutical has the right to import that product into the US.⁵² Imports of foreign pharmaceuticals may not have Food and Drug Administration (FDA) approval, which is specific to the manufacturer location, formulation, specification of the active ingredients, labeling, and many other features.⁵³

⁴⁷ *Omega S.A. v. Costco Wholesale Corp.*, 541 F.3d 982 (9th Cir. 2008).

⁴⁸ The US Tariff Act of 1930, section 526(a): ‘it shall be unlawful to import into the United States any merchandise of foreign manufacture if such merchandise or the label, sign, print, package, wrapper, or receptacle, bears a trademark owned by a citizen of, or by a corporation or association created or organized within, the United States, and registered in the Patent Office by a person domiciled in the United States.’

⁴⁹ The US Patent Act, USC:35-Title, section 271.

⁵⁰ *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng’g Corp.*, 266 F. 71 (2d Cir. 1920).

⁵¹ *Jazz Camera Photo v. Int’l Trade Comm’n*, 264 F.3d 1094 (Fed. Cir. 2001).

⁵² U.S.C.Federal food, drug and cosmetic act, section 381(d)(1) <<http://www.law.cornell.edu/uscode/text/21/381>> accessed 10 March 2013.

⁵³ Kyle (*n* 1)343-44.

Following to the President Obama's agenda to make healthcare cheaper in March 2009 'A bill to amend the Federal Food, Drug and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes' was introduced and referred to the US Senate with respecting committees. The Bill aimed to address the current situation under which the US consumers are charged some of the world's highest prices for prescription drugs. The Bill would have allowed US-licensed pharmacies and wholesalers to import FDA-approved medications from Canada, Europe and elsewhere. The legislation would have included further provisions to prevent pharmaceutical companies from obstructing trade, such as slightly altering formulations to prevent them from being imported or failing to supply Canadian pharmacies.⁵⁴ However the Bill was not enacted and was sent back to the committee.⁵⁵

The same fate was shared with the Bill introduced later on February 10, 2011 by the senator Olympia Snow.⁵⁶ This indicates unsuccessful attempts to allow parallel trade of pharmaceutical from outside in the US.

Even though that parallel trade in pharmaceuticals is not allowed or is rendered to be difficult in the US, it still appears through the backdoor via internet sales and threatens the profitability of the US pharmaceutical companies and has long-run implications to this end.

3.5. Comparison and discussion

The comparison concerning the parallel trade of pharmaceuticals showed some similarities and disparities. In both jurisdictions parallel trade is encouraged by the price differences, in Europe between southern European and Northern European Countries and regarding the US low prices in Canada play an influential role. However, unlike the EU the price is not the result of negotiations between pharmaceutical companies and government authorities in the US. Thus, this could work for pro parallel traders to defend it under the US jurisdiction. While in the EU pharmaceutical companies are asking the restriction of parallel trade on the basis that market is different from other sectors, since it is not governed by the principles of pure supply and demand.

⁵⁴ CMS, 'European Parallel Trade Review ' (2011),29< <http://www.cmslegal.com/European-Parallel-Trade-Review-2011-05-03-2011>> accessed 5 March 2013.

⁵⁵ See <<http://www.govtrack.us/congress/bills/111/hr1298>> accessed 5 March 2013.

⁵⁶ See < <http://www.govtrack.us/congress/bills/112/s319>> accessed 5 March 2013.

One of the main factors to not allow parallel imports in the US is the safety reasons and this can be clearly explained by the difference between the EU and the US constitutional structure. In the EU we are speaking about one European market which has the centralized system of authorization and safety protection, while in the US, this cannot be achieved since parallel trade is conducted from another country which has separate and different authorization system regarding drugs. Therefore, the US has legitimate right to restrict parallel trade for the sake of consumers' health protection.

Another difference detected, is that for the EU parallel trade is a means to remove obstacles and create one single market. The establishment of an internal market is at heart of the European Union, according to the Article 3(3) TFEU. The Lisbon Treaty has considerably broadened the foundations and the goals of the European unification setting up of an area without internal frontiers.⁵⁷

The same goals and challenges are not facing the US, due to the fact that the US is a federalist state, while the Union is not a state as such and aims to achieve economic cooperation between Member States.

Thus, as the state, the US can ban the parallel trade for the sake of protection of national market and profitability of pharmaceutical companies. As increasing numbers of US retail consumers have turned to Canadian-based internet pharmacies, the profit margins pharmaceutical companies enjoy have fallen.⁵⁸

However, the protection of national markets in the EU cannot be accepted as a justification if it includes the discrimination of products originated from the other members states and will be against the free movement rules.

Notwithstanding different approaches to parallel trade in two jurisdiction, the problem caused by it to the pharmaceutical companies remain the same; which is the threat to profitability reflected later on the R&D funding.

The EU is aware of the specificity of pharmaceutical sector. The Commission has recognized the particularities of the market in its Communication outlining an industrial policy for the pharmaceutical sector in the European Community:

⁵⁷ Steven Anderman, Ariel Ezrachi, *Intellectual Property and Competition Law* (Oxford University Press 2011) 304.

⁵⁸ Aidan Hollis, Peter Ibbott, 'How Parallel Trade Affects Drug Policies and Prices in Canada and the United States,' (American Journal of Law & Medicine. 32 (2006)) 205.

The pharmaceutical market is not a normal market. Companies channel competitive efforts into therapeutic innovation and continued improvements to existing products. ‘Competition between companies focuses on therapeutic innovation. Promotion activities with health professionals play a key role. Enterprises are therefore often less concerned about competing on prices, and rather concentrate on their costs, finances and sales volumes.’⁵⁹

Thus, the manufacturers of the pharmaceuticals have no reason to make life easy for parallel traders. They need to protect the future of their industry, which requires a 10-15 year horizon in developing new drugs.⁶⁰ Moreover, on average only one or two of every 10,000 substances synthesized in laboratories, will successfully pass all the stages to become marketable medicines.⁶¹ This means that the successful one out of 10000 substances, should recoup the investment and costs incurred not only for it but for the rest unsuccessful 9999. This indicates the sensitivity of pharmaceutical industry to parallel trade.

It was argued that Canadian internet trade may have reduced global drug manufacturer profits by roughly 1%. While this amount seems small over time this could have an impact on the speed of development of new useful medicines⁶².

Therefore, pharmaceutical companies try to justify restriction on parallel trade on the basis to invest in R&D. This is discussed below within the ambit of EU competition rules and in light of respecting case-law.

⁵⁹ Commission, ‘Communication outlining an industrial policy for the pharmaceutical sector in the European Community’ COM (93) 718, 17.

⁶⁰ REMIT Consultants, (n 41) 5.

⁶¹ EFPIA (n 33) 6.

⁶² Hollis and Peter Ibbott, (n 58) 206.

4. EU COMPETITION LAW IN PARALLEL TRADE CASES

4.1. Intersection between IPRs and Competition Law

Even though, competition and IP laws share the same policy goal to promote innovation for the sake of better products being developed, a tension arises between them⁶³, since EU competition rules provide an external system of regulation that applies to anticompetitive conduct not prevented by the internal system of regulation offered by IP Legislation.⁶⁴ Secondly, competition policy affects how IP owners may respond to parallel trade and those actions can be viewed as anticompetitive.⁶⁵

The achievement of proper balance between enforcement of competition rules and proper regard to IPRs comes at stake in the pharmaceutical sector. The current stand of the Courts regarding the restraints on parallel trade is analyzed in light of *Glaxo saga*.⁶⁶

4.2 The stand of Article 101 TFEU in agreements restricting parallel trade

The European Courts have, from and after *Parke Davis*,⁶⁷ established that the exclusivity right connected to an IPR is not itself anticompetitive under Articles 101 and 102 TFEU, only where the IPR is used to implement an agreement restrictive of competition then the prohibition comes into play.⁶⁸

This section discusses Article 101 TFEU in light of two cases *GlaxoSmithKline Services* and *Bayer*.

4.2.1. Dual pricing to combat the parallel trade: *GlaxoSmithKlein*

*GlaxoSmithKline Services v Commission of the European Communities*⁶⁹ is the third in a row in the attempts of this firm to shake off parallel traders.⁷⁰

⁶³ Steven Anderman, and Ariel Ezrachi, (n 57) 250.

⁶⁴ Ilkka Rahmasto, *Intellectual Property Rights, External Effects and Anti-trust Law* (Oxford university press 2002)

⁶⁵ Kyle (n 1) 340.

⁶⁶ It is often called so in the literature, since all case discussed except *Bayer* were against the actions of *GalxoSmithKlien* in different countries on different basis.

⁶⁷ See Case 24/67 *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm* [1968] ECR 81

⁶⁸ *Desogus* (n17) 144.

⁶⁹ Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited v Commission of the European Communities*[2009] ECR I-9291.

The factual background briefly is as follows: Glaxo Wellcome SA (GW), a subsidiary of GlaxoSmithKline Services Unlimited (GSK), applied a differentiated price system for some pharmaceutical products sold to its Spanish wholesalers. Condition on different price charged distinguished between lower prices in the case of domestic resale of reimbursable drugs to pharmacies or hospitals, and higher prices charged in the case of exports of medicines to any other Member State. The Commission had decided that GW had infringed Article 101(1) TFEU: since such a clause in an agreement must be considered to have as its object restriction of parallel trade as competition.

Both Courts GC and the CJEU dealt with the case and came to a different conclusion. The GC's decision seems more favoring GW, elaborating the application of Article 101(3) somewhat in detail.⁷¹

The GC disagreed with the Commission and pointed out that restriction of parallel trade is not per se violation of the Article 101 TFEU. Moreover, it is not sufficient to find that an agreement as such restricts parallel trade and partitions the common market. Rather it also requires an analysis designed to determine whether it has as its object or effect the prevention, restriction or distortion of competition on the relevant market, *to the detriment of the final consumer*.⁷²

The GC took into consideration the specificity of the pharmaceutical market which distinguishes it from other industry, since the prices of the medicines concerned were to a significant extent shielded from "the free play of supply and demand" as they are fixed by the Member States directly or indirectly.⁷³ According to Anderman workable competition presupposes that pricing mechanisms are functioning normally.⁷⁴ This is the one characteristic which is not functioning "normally" in relation to competitive forces in the pharmaceutical market.

Given this particular context, the GC had determined that it could not be presumed that clause in the agreement imposing dual pricing system would restrict competition to the detriment of the

⁷⁰ Edith Loozen, 'The workings of Article 101 TFEU in case of an agreement that aims to limit parallel trade (GlaxoSmithKline Services (C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P)', (E.C.L.R. 2010, 31(9)) 349.

⁷¹ Commission Decision 2001/791 'Relating to a Proceeding Pursuant to Article 81 of the EC Treaty (Cases: IV/36.957/F3-Glaxo Wellcome (notification), IV/36.997/F3-Aseprofar and Fedifar (complaint), IV/37.121/F3-Spain Pharma (complaint), IV/37.138/F3-BAI (complaint), IV/37.380/F3-EAEPIC (complaint))' [2001] OJ L302/1.

⁷² Case T-168/01, *GlaxoSmithKline Services Unlimited v Commission of the European Communities* [2006] ECR II-2669(emphasizes added by the author), paras. 118-19.

⁷³ *Ibid*, para.133.

⁷⁴ Steven Anderman and Ariel Ezrachi, (*n* 57) 18.

final consumer.⁷⁵ The Spanish intermediaries might well keep the advantage in terms of price which parallel trade might entail, in which case the advantage would not be passed on to the final consumer in the first place.⁷⁶ Since the Commission had “at no point” examined the “specific and essential characteristics of the sector”,⁷⁷ the GC held that the presence of a restriction by object had not been established.⁷⁸

The GC found that the Commission was correct in finding that dual pricing concerned the restriction of the competition by effect. However, the GC found that:

The Commission had failed to carry out a proper examination of Article 101(3) TFEU and had not substantiated its conclusion that it was not proven: (i) that parallel trade was apt to lead to a loss in efficiency by appreciably altering GSK's capacity for innovation; and (ii) that sales conditions were apt to enable a gain in efficiency to be achieved by improving innovation.⁷⁹ Therefore, the GC annulled its decision in that part and required a new evaluation.⁸⁰

The case has been appealed by the both parties to the CJEU, which found that the GC had erred in law as to its interpretation of Article 101(1) TFEU.⁸¹ The CJEU followed the well established case-law by stating that “in principle,” agreements aiming at limiting parallel trade ‘have as their object the prevention of competition’.⁸² It added that this principle also applies to the pharmaceuticals sector.⁸³ Furthermore, the CJEU 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. As well, Article 101 TFEU 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*. [...]”⁸⁴

Regarding GSK’s request for an exemption under Article 101(3) TFEU, the CJEU agreed with the GC stating that the Commission failed to take into account all the relevant evidence produced by GSK regarding the loss in efficiency associated with parallel trade or the gain in efficiency

⁷⁵ Case T-168/0 *GlaxoSmithKline*, (n 72), para.122.

⁷⁶ *Ibid*.

⁷⁷ Case T-168/01 *GlaxoSmithKline*, (n 72) paras. 133-34.

⁷⁸ *Ibid*, para. 147.

⁷⁹ Case T-168/01 *GlaxoSmithKline*, (n 72), para. 303.

⁸⁰ *Ibid*, paras 316-18.

⁸¹ In Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline*, (n 69),paras .64-65

⁸² *Ibid*, para. 59.

⁸³ *Ibid*, para. 60.

⁸⁴ In Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline*, (n 69),(emphasize added),para. 63.

procured by the dual pricing clause, and that such decision was, for this reason, vitiated by a failure to carry out a proper examination.⁸⁵

Comments:

Even though the CJEU stated that limitation of parallel trade was restriction by object contrary to the GC's finding, both agreed on the necessity to consider the application of Article 101(3) TFEU. The CJEU pointed out that an agreement should be assessed in light of factual arguments and evidences provided by the undertaking, in order to establish the applicability of the exemption under 101(3) TFEU and the burden of proof imposed on the undertaking, only requires to establish that the occurrence of the appreciable objective advantage is sufficiently likely.⁸⁶

It is obvious that the Courts adopted the interpretation of the entire Article 101 TFEU in accordance with its economic fundamentals. However, such an economic approach has to be made fit to measure the dual structure that characterizes that provision. Keeping in mind the basic assumption that Article 101 TFEU as a whole serves to enhance consumer welfare,⁸⁷ the question needs to be addressed what consumer welfare effects must be analyzed in the context of para (1) and respectively (3) of that provision.⁸⁸ A useful approach would be to link Article 101(1) TFEU to the effects of an agreement on allocative inefficiency, and Article 101(3) TFEU to the effects of an agreement on productive and dynamic efficiency.⁸⁹

Thus, the presence of negative welfare effects for final consumers in terms of supply or price would trigger the application of Article 101(1) TFEU. However, its enactment would depend on analysis of possible positive welfare effects under Article 101(3) TFEU. This means that restrictive agreements will only be prohibited when they on balance lead to a decrease of consumer welfare.⁹⁰

The negative aspect of the CJEU's judgment is to bring an ambiguity regarding the purpose of the competition and Article 101 TFEU as such. 'Article 101 TFEU aims to protect not only the interests of competitors or of consumers, but also the "*structure of the market*" and, in so doing,

⁸⁵ Ibid, paras. 93-96,118.

⁸⁶ In Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline*, (n 69), para.102.

⁸⁷ Loozen, (n 70), 4.

⁸⁸ The focus is on economic welfare rather than social welfare. The reason therefore being that social welfare focuses on the redistribution of welfare which is a political issue

⁸⁹ See also: O. Odudu, *The Boundaries of EC Competition Law: The Scope of Article 81* (Oxford University Press 2006).

⁹⁰ Loozen, (n 70), 4.

“competition as such.”⁹¹ The notions: “structure of the market” and “competition as such” in this context is quite puzzling. Although if we consider that these terms are referred ‘in a manner of which the additional goal of market integration affects the interpretation of the notion of restriction by object’⁹² the ambiguity would be cleared. Then it would be possible to say that according to this judgment, the CJEU is at the position that the ultimate goal of the Article 101 TFEU is the protection of consumer welfare and it is better achieved by promoting the single internal market. Further market integration ensures that undertakings can and must compete in a bigger market. Thus it further enhances competition and consumer welfare.⁹³

This case shows that the GC was more eager to recognize that these strategies adopted by the pharmaceutical companies are nothing but attempts to cope with the symptoms of a disease, which undermines their ability to finance the R&D essential to prevent their “product pipelines from running dry”.⁹⁴ While the CJEU’s judgment shows that the introduction of a more economic approach is more easily said than done.⁹⁵

However, the development of the case-law on parallel trade seems to question the traditional legal approach to restrictions of parallel trade: its effect on static and dynamic efficiency based on companies’ incentive to invest in innovation.

4.2.2. Supply restrictions to fight parallel trade: *Bayer*

The most widespread strategy used by pharmaceutical companies to cope with parallel trade is so-called “supply chain management” systems. It involves restricting the supply of product to a wholesaler to the amount corresponding to the wholesaler’s sales on the domestic market plus a limited margin.⁹⁶ Similar scenario was at stake in the case *Bayer*.⁹⁷

Bayer restricted supplies to its French and Spanish wholesalers so that they had sufficient stock to meet only domestic demand, thus limiting their ability to export to the higher priced UK

⁹¹ In Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline*, (n 69), para. 63.

⁹² Loozen, (n 70), 6.

⁹³ Ibid.

⁹⁴ David W Hull, Covington & Burling, ‘Parallel Trade of Pharmaceuticals and EC Competition Law’,(Life Sciences 2007/08) 125 <<http://www.cov.com/files/Publication/73dfa444-2c60-4710-ad4b-30e127fe5658/Presentation/PublicationAttachment/10debeb7-de7d-4f9a-a07a-359d00354794/Parallel%20Trade%20in%20Pharmaceuticals%20and%20EC%20Competition%20Law.pdf>> accessed 5 March 2013.

⁹⁵ Loozen, (n 70), 8.

⁹⁶ David W Hulland others, (n 94), 125.

⁹⁷ In 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.

market. The Commission had decided that *Bayer's* conduct was part of a continuum of commercial relations with the distributors and so constituted an agreement contrary to Article 101 TFEU.⁹⁸

The main legal issue before the Court here was that for a supply chain management system to be caught by Article 101 TFEU, there must be an “agreement” capable of falling within the scope of Article 101. The CJEU stated that:

The mere fact that a measure adopted by a manufacturer, which has the object or effect of restricting competition, falls within the context of continuous business relations between the manufacturer and its wholesalers is not sufficient for a finding that such an agreement exists.⁹⁹ Indeed, the evidence suggested that the distributors did everything possible to circumvent that policy. Accordingly, there was insufficient evidence to find a “concurrence of wills”, as required under Article 101 TFEU *Bayer's* policy was, in essence, a unilateral one.¹⁰⁰

Consequently, the CJEU upheld the GC’s judgment stating that action of a non-dominant company *Bayer* to prevent the parallel trade of its product did not fall under the rules prohibiting restrictive agreements because *Bayer's* action was unilateral.¹⁰¹

Comments:

Contrary to the *Glaxo*, the application of Article 101(3) TFEU in *Bayer* was not considered. As well the negative and positive effects to the consumer welfare in the scope of that Article was not discussed for a very simple reason, that Article 101 TFEU was found not to be applicable, since *Bayer's* supply chain managements system did not constitute an agreement.

The welcoming outcome of this case for the pharmaceutical companies is that the CJEU did not accept the Commission’s attempt to stretch Article 101TFEU to catch unilateral behavior. Thus, attempts of pharmaceutical companies to cope with parallel trade through supply chain management system which does not include the “concurrence of wills,” as to say an agreement, would not be caught by the EU competition rules, unless a company is a dominant.

Article 102 TFEU might be engaged in the similar situation when dealing with the unilateral conduct of a *dominant* company and this is discussed right below.

⁹⁸ Ibid, paras. 4-7.

⁹⁹ In Joined Cases C-2/01 P and C-3/01 P *Bayer*, (n 97), 114.

¹⁰⁰ Gavin Robert and Stephanie Ridley, ‘Parallel Trade in Pharmaceutical Sector: Scourge or benefit’ (E.C.L.R. 2006, 27(2), 91-95).

¹⁰¹ Joined Cases C 2/01 P and 3/01 P *Bayer*, (n 97).

4.3. Article 102 TFEU and parallel trade of pharmaceuticals

Actions adopted by pharmaceutical companies: dual pricing and limitation to supply entail not only Article 101 TFEU but also trigger Article 102 TFEU in particular circumstances. Hence, the role of the Article 102 TFEU is dealt in light of two cases *Syfait* and *Sot Lélos*.

4.3.1 Limitation to supply under 102 TFEU: AG Jacobs in *Syfait* v. AG Colomer in *Sot Lélos*

*Syfait*¹⁰² follows the case *Bayer* in footsteps; it likewise involves a strategy adopted by pharmaceutical company to combat parallel trade, by limiting the supply. Contrary to the case *Bayer* this situation could have been caught under the Article 102 TFEU.

This section analyses AG Jacobs' opinion in conjunction with AG Colomer's contradicting opinion in the case *Sot Lélos*, which involved the same facts as *Syfait*.

In this case, GSK stopped supplying its Greek wholesalers with its products because the wholesalers exported a substantial proportion of GSK's products to higher-priced Member States. When GSK subsequently reinstated supplies to wholesalers, it refused to meet their orders in full, in order to prevent parallel imports. Thus, the case concerned the extent to which unilateral action by a dominant pharmaceutical company to limit parallel trade constitutes an abuse of a dominant position and, in particular, whether it can be objectively justified.¹⁰³

However, *Syfait* has been dismissed by the CJEU on procedural grounds, since it was referred by the Greek Competition authority, which did not satisfy the requirement of being a court or tribunal for the purposes of Article 267 TFEU.¹⁰⁴ Thus, there is no judgment available on the merits of the case; rather we are left with valuable opinion of the AG Jacobs.

In *Syfait* AG Jacobs argued in open contrast with prior case-law under Article 102 TFEU¹⁰⁵ suggesting that a pharmaceutical company does not necessarily abuse its dominant position if it refuses to supply wholesalers in order to protect its commercial interests as long as an action is objectively justified. Jacobs summarized the case-law on refusal to supply as follows: a) Dominant companies may have the duty to supply where failure to do so would, for example, seriously disrupt competition between the company and the customer on a downstream

¹⁰² Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE* [2005] ECR I-4609.

¹⁰³ *Ibid.*

¹⁰⁴ Case C-53/03 *Syfait*, (n 102), paras 29-37.

¹⁰⁵ See for instance: Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities* [1978] ECR 207, 83.

market.¹⁰⁶ b) Dominant companies are not obliged to meet orders that are out of the ordinary and they are entitled to take reasonable steps in defence of their commercial interests.¹⁰⁷

AG suggested to take into account the specific economic and regulatory context while assessing an abuse.¹⁰⁸ On the basis of these considerations, Jacobs found that there was no *per se* abuse by Glaxo. He went on to determine whether there was any abuse at all, but couched this assessment in terms of whether there was any “objective justification” for the refusal to supply.¹⁰⁹ Jacobs put forward the following ground of objective justification:

The Price regulation: According to Jacobs it is impossible to ignore the pervasive and diverse regulation to which the pharmaceutical sector is subject both at national and Union levels and which, in his opinion, sets it apart from all other industries engaged in the production of readily traded goods. In particular, Member States intervene to limit the prices payable for medicinal products within their territory which leads to the price of pharmaceutical products varying largely between Member States. This in turn creates opportunities for parallel trade.¹¹⁰

AG Jacobs suggests that *the economics of the innovative pharmaceutical industry* is the ground of justification. Innovation is an important parameter of competition in the pharmaceuticals sector. The decision whether to invest in developing a new pharmaceutical product will obviously depend in part upon whether the producer expects to be able to make sufficient profits to recoup the cost of investment. Once the investment is made, however, that cost is sunk. It is therefore rational for an undertaking to supply its products on any market where the price is fixed above variable cost.¹¹¹ In addition, the legal and moral obligations imposed on pharmaceutical manufacturers make it difficult for them to withdraw products already marketed in low-priced Member States.¹¹² Therefore, there is a risk that, dominant pharmaceutical companies would delay the launch of new products in lower priced Member States. This would lead to a fall in the levels of output and consumer welfare generated by some pharmaceutical products and an even greater fragmentation of the market with different ranges of products available in Member States.

¹⁰⁶ Opinion of AG Jacobs in C-53/03 *Syfait* (n 102), paras 54,66.

¹⁰⁷ *Ibid*, para. 56.

¹⁰⁸ Opinion of AG Jacobs in C-53/03 *Syfait* (n 102), para. 68.

¹⁰⁹ *Ibid*, paras 69-71.

¹¹⁰ Opinion of AG Jacobs in C-53/03 *Syfait* (n 102), paras 79-81.

¹¹¹ *Ibid*, para. 89.

¹¹² Opinion of AG Jacobs in C-53/03 *Syfait* (n 102), para. 86.

Jacobs considering *consequences of parallel trade to end consumer* and purchasers of pharmaceutical products came to the conclusion that the benefits of parallel trade are ordinarily enjoyed by those who purchase the products at a lower price and parallel trade in pharmaceutical products does not necessarily result in price competition discernible to the benefit of the end consumer.¹¹³ Nor does parallel trade always result in price competition to the benefit of the national health care system which purchases pharmaceutical products, or the taxpayers who contribute to those funds.¹¹⁴ The price differential resulting from parallel trade is often absorbed by those involved in the distribution chain and rarely benefits the ultimate consumer.¹¹⁵

The opinion of AG Jacobs considers the effect of parallel trade in a long run and gives hope that one day prayers of pharmaceutical companies might be heard by the CJEU.

Proceedings in the Greek civil Courts continued in parallel. After the Athens Court of First Instance declared the wholesalers' allegations unfounded, an appeal was brought before the Athens Court of Appeals and it referred the same questions to the CJEU concerning the interpretation of Article 102 TFEU.

Four years after the AG Jacobs, AG Colomer delivered contradictory opinion. Even though, Colomer disagreed with Jacobs and found that limitation of supply was an abuse of a dominant position, he as well refused the reading of Article 102 TFEU as a *per se* prohibition of abusive conducts and accepted the application of a rule of reason in the antitrust analysis, through analyzing possible efficiency gains.¹¹⁶ It seems that Colomer took more economic considerations into account when assessing the abuse under Art 102 and suggested three grounds of justification for the dominant undertakings: *specificity of the market, the legitimate protection of their business interests, and proof of net positive economic effect.*¹¹⁷

Both AGs agree on that the pharmaceutical market operates somehow differently from other markets, since there is a strong intervention from the state side by regulating the prices. However, Colomer disagrees with Jacobs and suggests that price regulation does not create a situation capable to justify the supply restrictions, since such an intervention is balanced by the

¹¹³ Opinion of AG Jacobs in C-53/03 *Syfait* (n 102), para. 97.

¹¹⁴ *Ibid*, 98.

¹¹⁵ *Ibid*.

¹¹⁶ Opinion on AG Colomer in Joined cases C-468/06 to C-478/06 *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE* [2008] ECR I-7139, paras 71-72.

¹¹⁷ *Ibid*, para. 79,(Emphasize added).

strong role of pharmaceutical companies in price negotiation as they possess the patent on new product which can improve the health of a patient. This point is highly significant since the Member States are interested to get the new drugs, as it is their duty to ensure that a high-quality public health system is provided for patients.¹¹⁸

Colomer did not share Glaxo's argument that limitation to supply is the protection of the legitimate business interests to recoup the investment in R&D. According to AG, there is no direct negative link between the parallel trade and R&D. If the parallel importers gain from the situation existed it could be the fault of a pharmaceutical company as well, since they are free to design the distribution system; however they decided on a strategy which incorporated the Greek wholesalers as was considered more economically efficient and advantageous.

Regarding the economic efficiency argument AG Colomer stated that it is up to the dominant company to provide the argument about the efficiency gains from their abusive action, however he is at the position that such evidence has not been provided by Glaxo.

Comments:

Notwithstanding the fact that two AGs' opinions on the same case delivered at different times seem controversial at the first sight, it cannot be said that they are radically different. The common conclusion to be drawn is that supply restrictions are not abusive *per se* and it should be assessed in light of positive effects. Even if AG Colomer does not agree that price intervention by the government should cause different treatment of the sector, he still considers that economic analysis should be incorporated more heavily, in order to see whether there are welfare gains from such an allegedly abusive action. Thus, it is clear that even Article 102 TFEU unlike its preceding Article 101 TFEU does not have individual exemptions, that the rule of reason analysis should be still considered.

¹¹⁸ AG Colomer in *Sot. Lélos* (n 116), paras, 89,90.

4.4. The CJEU on the limitation to supply: *Sot Lélos*

*Sot Lélos kai Sia*¹¹⁹ is a last word in GlaxoSmithKline saga, which began in 2000. The case involved the opinions of two AGs delivered in different procedures at different times, concluded by the CJEU Judgment at second round in 2008.

The CJEU started dealing with the case by repeating the importance of parallel trade: ‘parallel imports enjoy a certain amount of protection in Community law because they encourage trade and help reinforce competition’¹²⁰. Thus refusal to meet the orders of an existing customer constitutes an abuse of the dominant position under Article 102 TFEU, when that conduct without any objective justification is liable to eliminate a trading party as a competitor.¹²¹

In the ambit of objective justifications the Court looked at the specificity of pharmaceutical market and it took the same approach as AG Colomer stating that nevertheless of state intervention pharmaceutical companies are able to influence the price through the negotiations.

The CJEU accepted that dominant company is entitled to protect its own commercial interests. However, a pharmaceutical company cannot refuse to provide “ordinary” orders of an existing customer, for the sole reason that customer exported part of the quantities ordered to other Member States with a higher price¹²², however the Court seems to leave room for maneuver for the pharmaceutical company when the issue concerns the orders that are out of the ordinary.¹²³

Comments:

The judgment is pragmatic and represents a partial victory for both sides of parallel trade debate in the pharmaceutical sector. While arrangements designed to limit parallel trade are unlikely to escape the application of Article 102 TFEU, the Court recognizes the ability of dominant pharmaceutical companies to protect legitimate commercial interests when dealing with parallel trade.¹²⁴ It states that restriction of parallel trade is not a per se abuse. Moreover, it should always be checked in light with objective justifications. The main victory for a pharmaceutical sector is that the CJEU recognizes the freedom of the pharmaceutical company to refuse the orders out of ordinary.

¹¹⁹ Joined cases C-468/06 to C-478/06 *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEEVE Farmakeftikon Proionton, formerly Glaxowellcome AEEVE* [2008] ECR I-7139.

¹²⁰ *Ibid*, para.37.

¹²¹ Joined cases C-468/06 to C-478/06 *Sot. Lélos*(n 119), para. 34.

¹²² *Ibid*, para. 70.

¹²³ Joined cases C-468/06 to C-478/06 *Sot. Lélos*(n 119),para .71.

¹²⁴ Peter Turner-Kerr, ‘Finally a bit of clarity for pharmaceutical companies; but uncertainties remain: judgment of the ECJ in *Sot Lelos kai Sia EE v GlaxoSmithKline AEEVE*’, (E.C.L.R. 2009, 30(2), 57-60).

One of the concerns is that the CJEU took old is gold approach by upholding the same formalistic approach established in earlier case-law; and avoiding the assessment of parallel trade impact on R&D by stating: ‘without it being necessary to examine the argument raised by GSK’¹²⁵, even though the analysis on this matter was long awaited and hoped that *Glaxo* dual pricing would bring some light in the debate around parallel trade.

4.5. A new approach through efficiency gains: Analysis and discussion

After having pursued, for almost 40 years, a policy aimed at protecting and encouraging parallel trade¹²⁶ through the firm prohibition of corporate conducts that restrict exports,¹²⁷ Union Courts have questioned the legal principles underpinning such a policy in the pharmaceutical sector.

By summarizing the case-law dealt above, it is clear, that Pharmaceutical companies are capable of avoiding competition rules and especially Article 101 TFEU through supply management strategies that are specifically designed to hamper parallel trade on pharmaceuticals according to the case *Bayer*, as long as the company is not in a dominant position. Furthermore, dual pricing under Article 101 TFEU can be justified within the scope of Article 101(3) TFEU and in this regard GC’s judgment in *Glaxo* seems to give hope to the pharmaceutical companies.

The positive overarching approach of two AGs’ opinions is that application of Article 102 depends on the rule of reason analysis, through possible efficiency gains. Unlike Article 101(3) there is no exemption under Article 102 TFEU¹²⁸, thus, the presence of an objective justification

¹²⁵ Joined cases C-468/06 to C-478/06 *Sot. Lélos* (n 119), para. 70.

¹²⁶ See : Case C -373/90 *Procureur de la République v X* [1992] ECR I-131, where the Court explained the rationale of this policy by affirming that “parallel imports enjoy a certain protection in Community law because they encourage trade and help reinforce competition”.

¹²⁷ The jurisprudence is particularly rich for cases under Art.81EC (now 101); see Case 78/70 *Deutsche Grammophon Gesellschaft GmbH v Metro-SB-Großmärkte GmbH & Co. KG* [1971] EC .487; Joined cases 56/64 and 58/64 *Établissements Consten S. à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community* [1966] ECR 429; Case 19/77 *Miller International Schallplatten GmbH v Commission of the European Communities* [1978] EC. 131; Joined Cases 32/78, 36/78,82/78 *BMW Belgium v Commission of the European Communities* [1979] ECR 2435; Case C-267/95 *Merck & Co Inc v Primecrown Ltd* [1996] ECR I-6285;

¹²⁸ AG Kirschner in his Opinion on Case T-51/9 *Tetra Pak Rausing SA v Commission* [1990] ECR II-309, in reply to Tetra Pak’s arguments that Art.82 EC should be examined in two stages, namely (1) whether the conduct was prima facie an abuse; and (2) whether it was objectively justified, affirmed that “it is not possible to read into Article [82] a set of criteria for dispensation”. Also Jacobs A.G. in his Opinion at [72],. Article 82 EC, by contrast with Article 81 EC, does not contain any explicit provision for the exemption of conduct otherwise falling within it. Indeed, the very fact that conduct is characterised as an ‘abuse’ suggests that a negative conclusion has been already reached...’

must be taken into account when assessing whether a conduct is abusive or not, following a dialectic process.¹²⁹

This effect-based approach, claimed by a large number of legal and economic scholars,³⁶ has been recently and more explicitly endorsed by the European Commission in the DG Competition Discussion Paper, which states that:

[W]hen applying the consumer welfare test, the assessment of dominant undertakings' conduct should consider whether such a conduct, besides harming consumers, also yields benefits to them. To this purpose, a potential reduction of consumer welfare should be weighed also against the possible efficiency gains resulting from that conduct.¹³⁰

A much greater use of economic theory in antitrust analysis has enlarged the scope of the application of the concept of “objective justification” based on dynamic efficiency gains arising from anticompetitive conduct.¹³¹ Such a trend could open the door for the pharmaceutical companies to justify their actions directed against parallel trade if efficiency gains to consumer welfare which could outweigh negative anticompetitive effects are proved.

However, the CJEU seems more cautious, and not as bold as AGs, by adhering to the old case-law, by referring to *United Banana* case as done in case *Sot lelos*.¹³² Such a vigilant approach from the CJEU is not straightforwardly bad, since the CJEU is aware more than anybody about the threat to accept different treatment for a specific industry. Most importantly the threat and damage which could be caused to the principle of free movement of goods, one of the main foundations of the EU, by accepting the restriction on parallel trade. Even though the prohibition contained in Article 34 TFEU cannot be invoked against undertakings, the obligation not to impede freedom of trade between Member States, applies to them in the form of Articles 101 and 102 TFEU.¹³³

¹²⁹ Claudia Desogus, ‘Parallel trade and Pharmaceutical R&D: the Pitfalls of the Rule of Reason,’ (E.C.L.R.2008,29(11), 54-65.

¹³⁰ Ibid.

¹³¹ See AG Jacobs’ Opinion in Case C-7/97 *Bronner GmbH and Co KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co KG* [1998] E.C.R. I-7791.

Among proponents of the efficiency defence as an objective justification see B. Sher, ‘The Last of the Steam-Powered Trains: Modernising Article 82’ (E.C.L.R. 2004, 243); J. Temple Lang, ‘Anticompetitive Abuses under Article 82 Involving Intellectual Property Rights’ in Ehlermann and Atanasiu (eds), *The European Competition Law Annual 2003* (2003),.589; and Gyselen, ‘Rebates: Competition on the Merits or Exclusionary Practices?’ in Ehlermann and Atanasiu (eds), *The European Competition Law Annual 2003* (2003),287.

¹³² Joined cases C-468/06 to C-478/06 *Sot. Lélos*(n 118),paras 34,39,40,49,50.

¹³³ Ibid, para 88, see also Case 22/78 *Hugin Kassaregister AB and Hugin Cash Registers Ltd v Commission of the European Communities* [1979] ECR 1869, para.17.

5. Discussion

5.1. Role of the EU competition policy in IPRs

As already seen, the tension between competition and IPRs is obvious in the cases of parallel trade of pharmaceuticals. The necessity to strike the correct balance has been recognized by the Commission:

....[I]ntervention on competition law grounds requires careful considerations where the application of Article 102 TFEU would lead to the imposition of an obligation to supply on the dominant undertaking. The existence of such an obligation –even for a fair remuneration may undermine undertakings’ incentives to invest and innovate and, thereby, possibly harm consumers.¹³⁴

According to the European Courts’ judgments, the exercise of an IPR should only be considered to be contrary to competition law on “exceptional circumstance.”¹³⁵ Furthermore, Organization for Economic Development and Cooperation (OECD) noted that ‘Investment in innovation requires a predictable legal system and, as a result, antitrust policy should be formulated to ensure that incentives to innovate are not unnecessarily weakened or destroyed.’¹³⁶ Gerber has studied the nature of competition law in the context of Modern history and explains some of the events which seem so alien in relation to pharmaceuticals.¹³⁷ According to him the necessity to protect competition is based on two aims: to protect normative and economic aims. ‘Normative aims consider that particular forms of competition are valuable for society, although their exact nature therefore varies with the society concerned. Economic aims consider that desirable levels of competition, and with them the benefits of increased wealth and innovation , are unlikely to be attained unless the legal system protects the competitive process.’¹³⁸

¹³⁴ Commission, Guidance on the Commission’s Enforcement Priorities in Applying Article 82 of the EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings(communication) COM (2009) OJ C45/0, para. 75.

¹³⁵ Case T-201/04 *Microsoft Microsoft Corp. v Commission of the European Communities* [2007] ECR II-3601 para 331; In *Microsoft* the General Court considered but ultimately rejected, Microsoft’s arguments that the imposition of a compulsory licence would reduce its incentives to innovate: paras. 697-701.

¹³⁶ OECD, ‘Competition, Patents and Innovation,’ < <http://www.oecd.org/competition/abuse/39888509.pdf> > accessed 25 February 2013.

¹³⁷ Davide Gerber, *Law and Competition in Twentieth Century Europe: Protecting Prometheus*, (Oxford University Press 1998) 334-91.

¹³⁸ *Ibid.*

In relation to the pharmaceutical sector, these would be a balancing of the need for these companies to make profits, while also being able to deliver the drugs necessary for modern society.¹³⁹

Schumpeter argues that innovation is best served where monopoly conditions operate-since this is the way in which the inventor can derive the best profit incentives in order to invest in R&D in the future.¹⁴⁰

Now, the thesis turns to assess the pros and cons of parallel trade in light of competition policy and IP considerations. The pharmaceutical sector has been at the centre of a number of recent controversies in EU competition law: on one hand the Commission's desire to encourage trade among Member States to create a single market and on the other hand the fact that parallel trade may undermine attempts by some national governments to reward and encourage investments in R&D.¹⁴¹

5.2. Pros and cons of parallel trade

In this concluding chapter economic perspective of pros and cons of parallel trade is discussed, especially in competition matters, where economic gains and losses are the factors to be considered.

The basic view around parallel trade is based on two arguments: first of all, parallel trade might reduce important 'inter-brand' competition between producers, but may be capable of promoting 'intra-brand' competition between dealers. Secondly, parallel trade might lead to abolishment of geographical price discrimination. Modern economics argues that price discrimination can be efficient and therefore pro-competitive. In line with these two sets of arguments, new economic insight challenges the traditional image of the parallel trader as the "holy warrior" of the internal market.¹⁴² The arguments around parallel trade from both sides is focused around consumer

¹³⁹ Hunter, Russell Graeme, *The pharmaceutical sector in the European Union-intellectual property rights, parallel trade and community competition law*, (Institute for the European Law at Stockholm University 2001) 46.

¹⁴⁰ See, Joseph A. Schumpeter, *Capitalism, Socialism & Democracy*, (George Allen & Unwin (Publishers) Ltd 1976).

¹⁴¹ Andrea Coscelli, Geoff Edwards, Alan Overd 'Parallel trade in pharmaceuticals: more harm than good?' (E.C.L.R. 2008, 29(8), 490-492, <<http://international.westlaw.com> >accessed 5 March 2013.

¹⁴² Josef Drexl 'Healing with Bananas-How Should Community Competition Law Deal with Restraints on Parallel Trade in Pharmaceuticals?' (Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 11-13, 2009), 6< http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1935285> accessed 10 March 2013.

well-fare, however welfare effects of parallel imports of pharmaceuticals are generally ambiguous¹⁴³ and two public policy goals are analyzed through implications of intra brand competition and price discrimination.

A major long-run public policy objective is to stimulate the innovation and development of new medicines. In particular, pharmaceutical producers shall benefit from the higher prices of medicines protected by a patent, in order to be able to cover high R&D costs.¹⁴⁴ On the other hand, public policy should also ensure broad access to affordable existing medicines in the short-run.

Hence there is a trade-off between access to affordable medicines in the short-run and higher (monopoly) drug prices to stimulate R&D in the long-run.¹⁴⁵

5.2.1. Pros of parallel trade

As already seen and discussed, on several occasions the CJEU as well as the Commission have regarded parallel trade as an acceptable conduct fulfilling free movement requirements and providing price competition in a market.

According to European Association of Euro-Pharmaceutical Companies (EAEP), Parallel distribution of medicines provides significant savings to governments, health insurers and patients by making original, innovative medicines available at a lower cost.¹⁴⁶ The benefit from parallel trade can be categorized as following:

5.2.1.1. Savings –social welfare

It is suggested that parallel trade would stimulate savings both directly and indirectly. Direct benefits would derive from the lower prices paid by patients, which in turn entail lower reimbursement costs for health care systems and lower premium for health insurance. The

¹⁴³ Frank Muller-Langer, 'An Analysis of the Welfare Effects of Parallel Trade Freedom' (German Working Papers in Law and Economics, Volume 2008 Paper 9), 2 <<http://econpapers.repec.org/paper/bepdewple/2008-1-1225.htm>> accessed 25 February 2013.

¹⁴⁴ Ibid.

¹⁴⁵ See: Maskus (2001) 23.

¹⁴⁶ The European Association of Euro-Pharmaceutical Companies (EAEP) is a Brussels-based non-profit making organization, which regroup the European licensed parallel distribution industry, championing the industry's achievements and the benefits of its products. Through national associations and individual company membership, it encompasses over 70 firms from 16 countries in the European Economic Area (EEA). <<http://www.eaepc.org>> accessed 15 February 2013.

indirect benefits may be from the competitive pressure put on manufacturers by parallel importers that drives down patented products prices, or decelerates their increase.¹⁴⁷

Savings appears in importing countries. For instance in Ireland and Sweden - a parallel traded product must offer savings to the state before it is reimbursed.¹⁴⁸

Savings can be detected in exporting countries as well. Wholesalers in exporting countries are legally obliged to meet domestic demand first - in fact most countries impose, through national law or a voluntary code of conduct, a so-called "public service obligation"; But the distribution chain - wholesalers and community pharmacies - needs a certain level of income to provide the prompt and highly efficient service. Additional income from margins with parallel trade sales lessens the burden on the social healthcare system of exporting countries.¹⁴⁹

Savings from parallel trade are reflected on the patients. Rothnie observes that 'since the parallel importer will rarely incur these (pre-sales marketing and after-sales service) costs and so can sell more cheaply than the authorized outlets If they stop providing these services, though, it is quite possible that consumers would be less well off.'¹⁵⁰ For instance: In Belgium, Denmark, Finland, France, Greece, Luxembourg, Norway, Portugal, Spain and Sweden, the majority of patients pay a share of the cost of prescribed medicines they consume, so use of cheaper parallel-traded products will mean lower out-of-pocket demands.¹⁵¹

5.2.1.2. Brings competition: Intra-brand competition

Proponents of parallel trade argue that it enhances competition. Market in pharmaceuticals requires the unhindered free movement of products — private companies cannot erect barriers to undermine this without distorting intra-brand competition.

European Institutions have traditionally given a certain degree of protection to parallel trade, in the belief that it fosters *intra-brand* competition and promotes integration through intrastate trade.¹⁵²

¹⁴⁷ Claudia Desogus, 'Antitrust Issues in the European Pharmaceutical Market: an Economic Analysis of Recent Cases on Parallel Trade' 18, < http://www.upf.edu/cres/_pdf/wp60_desogus.pdf. > accessed 5 April 2013; See as well: Coscelli and others, (n 141).

¹⁴⁸ EAEPC, <http://www.eaepc.org/parallel_distribution/who_gains.php?n=2> accessed 10 March 2013

¹⁴⁹ Ibid.

¹⁵⁰ Warwick A. Rothnie (Chicago economic efficiency school representative), *Parallel Imports* (Sweet&Maxwell 1993), 503-505.

¹⁵¹ EAEPC, (n 148).

¹⁵² See the Case C-373/90 *Criminal Proceeding against X*, [1992] ECR I-131; (where the Court said that "parallel imports enjoy a certain protection in Community law because they encourage trade and help reinforce Competition), para. 12.

Following the views expressed by EAPEC parallel trade allows regulators to avoid implementing other more interventionist or market-distorting cost containment measures, giving wholesalers, pharmacists and patients a choice.¹⁵³

5.2.1.3. Generates wealth

Pro parallel traders argue that it *Generates wealth*, through creating new European businesses and new European jobs, often in economically-deprived regions, as well boosts the infrastructure for production and distribution in the countries of supply, as well as increasing foreign exchange earnings there.¹⁵⁴ Noteworthy to say that the efficiency claims advanced by the research based pharmaceutical industry is unsubstantiated — i.e. ‘there is no evidence that partitioning the common market would spur on global investment in inter-brand innovation.’¹⁵⁵

5.2.2. Cons of parallel trade

In response to the pro parallel trade arguments discussed, this section puts forward counter arguments. The adverse effects of parallel trade on price discrimination and impact on incentives to future R&D is discussed.

5.2.2.1. Savings: social-welfare challenged

Profit is made by parallel traders not by consumers and this is linked to the specificity of the pharmaceutical market, as substitution does not operate at the level of patients. Patients are in fact price insensitive, as most of their pharmaceutical expenditures do not come out of their pocket but are covered either by the national health care system, or by private insurance. The reimbursement system, however, creates a departure from the classical market functioning, as consumers use products that an agent – the government - pays for him/her.¹⁵⁶ However, it cannot be excluded that savings made by the government is eventually reflected on the individuals in the end through the budget distribution. Though, the measurement of such benefits is not straightforward, because their existence depends on features of the health care system and is not always immediately visible or easily accountable.

¹⁵³ EAPEC, <http://www.eapec.org/parallel_distribution/who_gains.php?n=2> accessed 10 March 2013.

¹⁵⁴ Ibid.

¹⁵⁵ Nadia De Souza, ‘Competition in Pharmaceuticals: the challenges ahead post AstraZeneca’, (Competition Policy Newsletter Number 1 2007) 40.

¹⁵⁶ Desogus, (n 147) 9.

The lowering of prices can be beneficial to the consumers in the imported countries; however it can have adverse effect on the low price, exporting countries. According to Vicien¹⁵⁷ this could bring the result that manufacturers may instead opt for a policy of refusing to sell their products in the cheapest markets, or even locking manufacturing plants out which of course has knock-on effects on employment. Moreover, parallel trade undermines the pricing policy of other Member States that have opted for higher prices in order to encourage R&D.¹⁵⁸

5.2.2.2. Parallel trade v. Price discrimination

“There are no miracles from miracle drugs that people cannot afford.”¹⁵⁹

Benefits of the new drugs should be affordable to the patients, and this is the driving force for price negotiations with pharmaceutical companies, which results in price discrimination among different countries. Even though there are some concerns regarding the fairness of price discrimination done by monopolistic companies which is not the topic of discussion of this thesis, one should bear in mind that there would surely be wide support for the view that it is fair to apply differentiated mark-ups for patented medicines according to the ability to pay.¹⁶⁰

Price discrimination is endangered by parallel trade. Parallel trade makes it harder for producers to charge different prices to consumers in different countries. Therefore, parallel trade is in the interest of consumers in the country of import where the ability to pay is higher,¹⁶¹ whereas parallel trade forces the producer to raise prices in countries where the buying power is considerably lower. In the European market, parallel trade has therefore the tendency to harmonize the level of consumer prices.¹⁶²

The threat posed by parallel trade to price discrimination through harmonizing the prices was considered by Post-Chicago school.¹⁶³ It was suggested that if parallel trade would be allowed this would undermine the ability of firms to price discriminate. The reason is straightforward as

¹⁵⁷ Concepcion Fernandez Vicien, 'Why parallel imports of pharmaceuticals should be forbidden', (ECLR 1996, 17(4), 219-225, <<http://international.westlaw.com>> accessed 5 March 2013

¹⁵⁸ See Frank Müller-Langer, 'A Game Theoretic Analysis of Parallel Trade and the Pricing of Pharmaceutical Products' (German working papers in Law and Economics volume 2007 paper 6) <<http://econpapers.repec.org/paper/bepdewple/2007-2-1200.htm>> accessed 11 February 2013.

¹⁵⁹ U.S. Senator Byron Dorgan, Democrat of North Dakota *cited in* Miyase Yesim Köksal, 'Reference Pricing Making Parallel Trade in Pharmaceuticals Work', (working papers in economics, University of Gothenburg 2011 No 367), <https://gupea.ub.gu.se/bitstream/2077/20431/4/gupea_2077_20431_4.pdf> accessed 6 March 2013.

¹⁶⁰ Glynn, Dermot, 'Article 82 and Price Discrimination in Patented Pharmaceuticals: the Economics' (E.C.L.R. 2005 26 (3) 135-143.

¹⁶¹ Drexl, (n 142) 12.

¹⁶² Ibid.

¹⁶³ Since 1992, the Post-Chicago school has been gaining ground.

Demaret explains: ‘When domestic laws no longer permit import restrictions, parallel imports become possible between territories; it becomes unfeasible to quote different prices in each territory for the patent protected good.’¹⁶⁴ Distributors or other middlepersons will engage in arbitrage, until a law of one price predominates.¹⁶⁵

But, why would uniform price have adverse effect on pharmaceutical business? The answer is quite simple, according to Ramsey and Boiteux, the most efficient way to cover some fixed cost of production is to implicitly tax those markets that will be least affected by higher prices, *i.e.* those with a lower elasticity of demand.¹⁶⁶ Put differently, ‘the value of patent rights depends, to a certain extent, on “the scope for price discrimination within the area of exhaustion.”¹⁶⁷

In order to fight intra brand competition pharmaceutical companies could be forced to introduce more harmonized price and by doing so deprive the possibility to the most efficient and fairest way for patent holders to charge different prices in different parts of the world market according to ability and willingness to pay and thus, this could have long-run effect on inter-brand competition.

5.2.2.3. Intra-brand competition v. Inter-brand competition

The question is whether pharmaceutical companies are able to cope with inter-brand competition, when intra-brand competition is protected and facilitated? It is generally held that a producer who has to sustain competition with other producers ‘inter-brand competition’ will usually not be able to harm competition by vertically restricting freedom of dealers to compete. On the contrary, it is assumed that such producers will structure their distribution systems in a way that their ability to compete with other producers is enhanced, as pharmaceutical companies try to do through dual pricing or supply limitation as illustrated in previous sections. Vertical restraints are therefore held to be efficient and pro-competitive, at least if the producer is not

¹⁶⁴ Paul Demarets, *Territorial Restrictions, and EEC law: A Legal and Economic Analysis* (Studies in Industrial Property and Copyright Law, Vol. 2, Freidrich-Karl Beier et al. eds., 1978), 71.

¹⁶⁵ Clause E. Barfield, Mark A. Groombridge, ‘ Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy’, (Fordham Intellectual Property, Media and Entertainment Law Journal, Volume 10, Issue 1, 1999)230

<<http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?Article=1181&context=iplj>> accessed 13 February 2013.

¹⁶⁶ Glynn, Dermot, ‘Article 82 and Price Discrimination in Patented Pharmaceuticals: the Economics’ (E.C.L.R 2005 26 (3) 135-143.

¹⁶⁷ M. Ganslandt & K. E. Maskus , ‘Parallel Imports and Pricing of Pharmaceutical Products: Evidence from the European Union’, (Journal of Health Economics 23 (2004) 1037.

market-dominant. This is why, nowadays, there is a trend to consider giving up the ban on vertical market partitioning along the borders of EU Member States.¹⁶⁸

The same consideration is detected in AG Jacobs opinion on *Syfait*. He applied an analytical approach which came close to the general recommendation of the Commission for its more economic approach in balancing pro-competitive effects on inter-brand competition with the anticompetitive effects on intra-brand competition.¹⁶⁹ Shortly, Jacobs applied a balancing approach, by comparing the effects on inter-brand and intra-brand competition, and finally recommended allowing the restraint on parallel trade in view of promoting inter-brand competition. A similar balancing approach had been applied by the GC in its *GlaxoSmithKline* decision.¹⁷⁰

Thus, when one argues for the benefit of intra brand competition through parallel trade the implication of it on inter-brand competition should be taken into account, which leads to the next argument, particularly the effect of parallel trade on R&D.

5.2.2.4. R&D and Dynamic efficiency losses

The pharmaceutical industry is based on significant investments in innovation,¹⁷¹ which is one of the main factors determining the competitiveness of a company in the sector. Pharmaceutical research is long and costly. It takes 10 to 12 years and the average cost of researching and developing an entirely new medicinal product, is estimated at EUR 200 million.¹⁷²

The size of such expenditures requires the companies operating in this sector to recoup R&D costs through a constant and consistent flow of profits, in order to preserve their incentive to invest in research in the long run.¹⁷³

In this regard, Stuart Schweitzer notes that the ‘threat of cheaper versions of the patented drugs reentering the primary markets of the United States, Europe and Japan is serious.’¹⁷⁴ The

¹⁶⁸ D. Waelbroek, ‘VerticalA: 4 years of Liberalisation by regulation n. 2790/99 after 40 years of legal (block) regulation’, in H. Ullrich (ed.), *The Evolution of European Competition Law*(, Cheltenham, UK and Northampton, MA, US, Edward Elgar, 2006,)85, 99-105.

¹⁶⁹ Commission, ‘Guidelines on the application of Article 81(3) of the Treaty,’ COM (communication notice) (2004) OJ C101, para. 17.

¹⁷⁰ Case T-168/01 *GlaxoSmithKline* (n 72), para. 296.

¹⁷¹ Dimasi, Hansen and Grabowski, ‘*The price of innovation: new estimates of drug development costs*’, (*Journal of Health Economics*, 2003, n. 22), 151, where it is estimated that the cost of developing and bringing to the market a new drug is about eight hundreds millions dollars in year 2000.

¹⁷² Concepcion Fernandez Vicien, ‘Why parallel imports of pharmaceutical products should be forbidden’ (*E.C.L.R.* 1996, 17(4), 29-225.

¹⁷³ Desogus, (n 147).

¹⁷⁴ AvStuart O. Schweitzer, *Pharmaceutical Economics and Policy*, (Oxford University press 2007) 229.

research-based pharmaceutical industry's ability to develop innovative new drugs is also jeopardized by the practice of "cherry-picking major products, those which have improved therapeutic benefits."¹⁷⁵ Parallel traders most often trade in "sure-bets," or products just recently released that provide the bulk of profits for pharmaceutical companies.¹⁷⁶

Therefore, greater encouragement of parallel imports is likely to have an exaggerated effect on both ability and incentives to carry out desirable R&D.¹⁷⁷

In light of foregoing, pharmaceutical companies, for instance GSK argued that parallel imports, could reduce the resources available for R&D, as could any other form of price competition.¹⁷⁸ Therefore, through the elimination of profit losses caused by parallel trade, the company would have availed itself to fully exploit the value of its patent, thus stimulating further research and promoting dynamic efficiency and consumers' welfare.¹⁷⁹

Total appropriation of all possible returns does not necessarily foster more innovation.¹⁸⁰ Even though, it is difficult to establish the direct link between parallel trade and reduced investment in R&D such a possibility cannot be excluded either. Furthermore, the impact that parallel trade has on dynamic efficiency is not the same in all cases, and certain limitations on a property owner's right to exclude competitors may have only a marginal effect on investment decisions.¹⁸¹ Thus it appears more appropriate to say that, while parallel trade may limit incentives to innovate, the magnitude of that risk varies and should be assessed on a case-to-case basis.

¹⁷⁵ National Economic Research Associates (NERA), *Survey of Parallel Trade*, (May 1997), Key Conclusions.

¹⁷⁶ Barfield and Groombridge, (n 165) 195.

¹⁷⁷ Rothnie, (n 150) 505.

¹⁷⁸ Regarding the negative effect of parallel trade on profits and on the incentive to innovate for pharmaceutical companies, see Patricia M. Danzon, 'The Economics of Parallel Trade' (Pharmaco Economics Volume 13, Issue , 1998), 293, 300.

¹⁷⁹ However, the theoretical literature is not unambiguous with regards to the effect of parallel trade on manufacturers' profits. Recent literature, in fact, pointed at conditions like the presence of price regulation, where this can be positive. See: R.H. Ahmadi and B.R. Yang, 'Parallel Imports: Challenges from Unauthorized Distribution Channels' (*Marketing Science* (2000) 19(3) , 279; H. Raff and N. Schmitt, 'Why Parallel Trade may raise Producers Profits' (CESIFO Working Paper No.1503, 2005); P. Pecorino, 'Should the US allow prescription drug re-imports from Canada?' (University of Alabama Economics Working Paper No.01-01-04., 2002).

¹⁸⁰ M.A. Lemley, 'Property, Intellectual Property and Free Riding', (Texas Law Review(2005) 83), 1031, 1057 <<http://heinonline.org/HOL/LandingPage?collection=journals&handle=hein.journals/tlr83&div=30&id=&page=>> accessed 17 March 2013.

¹⁸¹ See; Ian Ayres and Paul Klemperer , 'Limiting Patentee's Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies,' (Yale Law School, no. 97, 1999), 987-990, who affirmed that '*unconstrained monopoly pricing is not a cost-justified means of rewarding patentees because the last bit of monopoly pricing produces large amounts of deadweight loss for a relatively small amount of patentee profit. [...] Restricting the patentee's monopoly of a small amount is likely to increase social welfare because the benefit of reducing the deadweight loss of supra-competitive pricing is likely to outweigh the cost of a slightly lower incentive to innovate* < http://digitalcommons.law.yale.edu/fss_papers/1256/> accessed 12 March 2013.

5.3. Possible defence under 101 and 102 TFEU

It has been shown that parallel trade might have an adverse impact not only on future R&D as such, but through declining the incentive to R&D might affect consumer welfare, though, this finding is not straightforward. In light of this consideration, let's turn to the possible defence of the restriction of parallel trade within the scope of 101(3) and 102 TFEU by summing up the previously discussed case-law.

Nowadays, industrial economists tend to require consumer harm as evidence of anticompetitive conduct.¹⁸² This is due to the fact that consumer welfare and general welfare are held to be maximized at the same equilibrium of perfect competition.¹⁸³

5.3.1. Defence under Article 101(3) TFEU: Efficiency gains

The issue of striking a balance between the interests of different consumer groups was actually on the table in the Spanish *GlaxoSmithKline* case as discussed above. The GC noted that the Commission itself accepted the ambiguous impact of parallel trade in medicines on the welfare of final consumers. Unless parallel trade can operate dynamically on prices, it creates inefficiencies because the financial benefit occurs to the parallel trader rather than to the healthcare system or the patient.

Contrary to the Commission, the GC accepted GlaxoSmithKline contention that parallel trade reduces the company's capacity to engage in inter-brand competition and that the dual pricing scheme would lead 'to a gain in efficiency for inter-brand competition in so far as it will enable the undertakings capacity for innovation to be increased.'¹⁸⁴

Full assessment of the efficiency argument is not an easy task though. It involves addressing in detail the likelihood that a company would invest in R&D, a significant part of the increased funding that would result from its dual-pricing policy. This in turn may involve addressing such questions as the relative amount of funding that would be invested in marketing as opposed to

¹⁸² Drexl, (n 142) 21.

¹⁸³ On the debate as to whether competition law should apply a consumer-welfare standard or a total-welfare standard, where the two exceptionally differ, See: J. DREXL, 'Competition Law as Part of the European Competition', in A. VON BOGDANDY & J. BAST (eds), *Principles of European Constitutional Law*, (Oxford, Hart Publishing, 2009 (forthcoming)), at section V.2.

¹⁸⁴ Case T-168/01, *GlaxoSmithKline* (n 72) para. 255.

R&D; as well, the relative importance of marketing expenditure in raising awareness of a product emerging from the R&D pipeline.¹⁸⁵

The GC case which in most way has been upheld by the ECJ shows the trend that actual effect on consumer welfare should be fully assessed in the legal and economic context under 101 TFEU and it is not permissible for a competition authority to reject a claimant's Art.101(3) arguments without properly weighing up those arguments. This trend in light with Article 2 of Regulation 1/2003¹⁸⁶ places the burden on pharmaceutical companies to show the efficiency gains of such an anti competitive action.

Since so much detailed assessment is needed and very little can be taken for granted in the case of pharmaceutical sector, one thing is clear that the doors for the room of efficiency gains for pharmaceutical companies are opening slightly but visibly.

5.3.2. Defence within Article 102 TFEU

As AG Colomer suggested, accepting the idea of per se abuse of a dominant position under 102 TFEU would run counter to the proposition and it is necessary to examine each case within the economic and legal context in which it arose.

Thus, it follows that the substantive test for the application of Article 102 TFEU should be based on the effect of the company's conduct on consumer welfare.¹⁸⁷ Article 102 TFEU does not prohibit unilateral conduct of a market dominant undertaking, the challenge lies in finding the correct criterion to distinguish lawful 'competition on the merits', which might even result in the exclusion of inefficient competitors, from illegal abuse.¹⁸⁸ Here, economists typically rely on consumer harm, since it is for the consumers that undertakings engage in competition in the first place and 'it is only by requiring consumer harm that enforcers can avoid the fallacy of protecting competitors, instead of protecting competition.'¹⁸⁹

¹⁸⁵ Richard Eccles, 'Parallel exports in the pharmaceuticals sector: taking nothing for granted'(E.C.L.R.2007 E.C.L.R. 2007, 28(2), 134-142.

¹⁸⁶ Council regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ L 1/1.

¹⁸⁷ See among other: Case C-310/93 *BPB Industries plc and British Gypsum Ltd v Commission of the European Communities* [1993] ECR. II-389, 65, 66, which held that promotional payments made by a dominant supplier to a customer in return for an exclusive purchasing commitment are "a standard practice forming part of commercial cooperation between a supplier and its distributors" that "cannot, as a matter of principle, be prohibited", but rather must be assessed in the light of their effects on the market in the specific circumstances.

¹⁸⁸ Drexl, (n 142) 22.

¹⁸⁹ See EAGCP: 'Report: An Economic Approach to Article 82', July 2005, p. 2 *et seq.* <http://ec.europa.eu/dgs/competition/economist/eagcp_july_21_05.pdf> However, there is a controversial approach

In considering the welfare implications of a conduct restricting parallel trade, it is necessary to consider two dimensions: the short-term harm to consumers (or losses in static efficiency) and the long-term benefits to consumers (or gains in dynamic efficiency).

Following the so-called “rule of reason” ‘standard, *ex post* static efficiency gains, maximized by an obligation to deal, should be weighed against the *ex ante* dynamic efficiency gains, which could be preserved by not imposing such a duty.’¹⁹⁰

On this view, a pharmaceutical companies actions aiming to restrict parallel trade is an abuse of a dominant position when and where static losses prevail over dynamic gains, after the close assessment and conduction the proportionality test.

The consumer harm requirement of modern industrial economics is however criticised from the perspective of the Austrian School. See: F.A. Von Hayek, ‘Competition as a Discovery Procedure’, in F.A. von Hayek, *New Studies in Philosophy, Politics and Economics and the History of Ideas*, (Chicago, University of Chicago Press, 1978), 179, it is argued that enforcers cannot rely on consumer interests as a yardstick for identifying harm to competition if it is competition alone that can produce the information on what consumers really want.

¹⁹⁰ Desogus, ‘Parallel trade and pharmaceutical R&D: the pitfalls of the rule of reason’, (n129) 54-65.

6. Conclusion

The objective of this thesis was to examine the possible justifications of restraints on parallel trade by pharmaceutical companies within the ambit of the EU competition rules. In this regard the thesis analyzed the legal stand of parallel trade based on IPR exhaustion in the EU and the US. After the comparison, a conclusion was made that there is a different attitude to the legality of parallel trade in the two jurisdictions and this is incited by different market goals.

The main argument against the legality of restrictions on parallel trade in the EU context is the very objective of market integration which does not appear as an obstacle for illegality of parallel trade in the US. According to Article 3(1) of TEU the Union aims to promote the wellbeing of its people and to this end the EU establishes an internal market. This exemplifies that the internal market is at the heart of the Union. In addition, this is neatly tied to the EU's choice to make regulatory integration, through price control in order to guarantee that the patient in poorer countries has access to medicines. However, this system is not considered by the CJEU as a decision against integration or opening the way to the restrictions on parallel trade which has been analyzed and illustrated by case-law in Chapter 3.1.1.

Old EC treaty had the Article 3(1) (g), which explicitly stated that the internal market included the system where competition is not distorted. The Lisbon Treaty removed that Article. This can be seen as a step taken towards less formalistic approach and giving more emphasize to competition policy. However, one should bear in mind that even the Lisbon Treaty does not have Article 3(1) (g), the same wording is repeated in the Protocol for Internal market and Competition. By virtue that the protocol has the same legal binding nature this does not bring crucial change. Moreover, from the name of the protocol one could argue that this title furthermore, marries internal market and competition. In addition, the Lisbon Treaty introduced the provision about competences and in Article 3(1) (b) TFEU it states that the EU has an exclusive competence in establishing the competition rules for the functioning of the internal market. This indicates that the EU competition rules indeed play an important role in proper functioning of the internal market and moreover serve as a tool for the internal market. Therefore, this argument has been considered as a back line of the whole research, while assessing the accommodation of restrictions on parallel trade within the EU competition rules.

Chapter 4 analyzed the European Courts attitude towards the restriction on parallel trade within the EU Competition rules. It can be concluded from the case-law analysis that if protection of the

internal market without frontiers places obligation on the Member States to remove all obstacles to free movement of goods through the Article 34 TFEU, the same aim is achieved through competition rules. They reach private parties-companies and prohibit the actions which are aimed to partition the market, by doing so competition rules enforce and protect the main goal of integration for the proper functioning of internal market.

Therefore, even after 50 years of European integration it is not yet time to give up this specific objective of competition law in favor of a pure efficiency approach.

However, the analysis conducted shows that the Courts and more AGs still consider efficiency gains of restriction on parallel trade. Since the protection of parallel trade is not itself the aim of the EU, rather it serves the goal of proper functioning of the internal market. Internal market is not the sole aim of the EU, but according to Article 3(3) TEU establishing competitive social market, which promotes the scientific and technological advancement, in order to achieve the well-being of its people is its aim as well. So, the EU aims to promote peace and well-being of its people and internal market is a tool for that. Such an understanding of the EU system would not be contrary to the new trend to seek the justification of the restrictions on parallel trades for the sake of consumer welfare through maintaining the incentive for R&D.

The pros and cons around the parallel trade were discussed in Chapter 5. The difficulties of achieving straightforward attitude towards the benefit or losses caused by parallel trade in pharmaceutical business were considered. This issue seems more complicated in research based pharmaceutical industry, the success of which is dependent on continued and long-run costly researches, requiring huge investment. However, it could be undermined by parallel trade through decreasing the profit and that would have a long-run implication on consumer welfare. Therefore, this is the main argument put forward by the pharmaceutical companies.

The analysis shows that the European Courts are aware of possible side effects of parallel trade in pharmaceutical industry and while applying the competition rules tend to consider the possible efficiency effects of anticompetitive actions.

In *C-501/06 P GlaxoSmithKline* the CJEU took more cautious approach and stated that competition laws are designed to protect not only the immediate interest of individual competitors or consumers, but also to protect the structure of the market and the competition as such. One could say that by doing so the CJEU rejects to consider pure effects on consumer and adds structure of the market and competition as such.

Even though, the terms structure of the market and competition as such seem obscure, they mean more than explicitly stated. It can be understood that the CJEU rejects to consider only immediate effects on consumer, i.e. elimination of intra-brand competition having static efficiency effect on consumer through depriving the possibility of the price choice. Moreover, the CJEU goes further and takes into account the long run effect on the market and competition as such. Thus, the CJEU considers value of inter-brand competition and by doing so assesses the impact on the consumer well-fare beyond the immediate.

However, this does not mean that the pharmaceutical companies would be given the possibility to freely justify the restriction of parallel trade by simply relying on efficiency gains and the investments necessary for the R&D. The Contribution of restrictive agreements to the promotion of innovation has to be shown, and there has to be a direct link between both. It is not sufficient to claim a general context between increased profits and stronger R&D activities. Therefore, it is not sufficient to say that without parallel imports the undertakings in question would earn higher profits which would be invested in R&D. In this regard, active and augmented use of Article 101(3) TFEU could provide the safe harbor for the pharmaceutical companies.

The previous analysis show that the CJEU is not against considering the economic aspects of the case, moreover, if the direct link is proved by pharmaceutical companies, there is higher probability that the actions will survive the application 102TFEU, as has been stated this Article does not considers as such a per se abuse of dominance.

On one hand, the pharmaceutical company does not need to prove long-run efficiency gains and can escape the competition rules if it designs supply management system in a way which does not amount the agreement as was in *Bayer*. On the other hand, more prudence is required if company is dominant, then supply management system may not have the same outcome as in *Bayer*. However, when the company is dominant, following the case *Sot Léllos*, there is no need to defend under the rule of reason, if the pharmaceutical company refuses to supply orders which is out of ordinary. Though, the restrictions on supply should not go beyond what is strictly necessary, as well should also allow competition among wholesalers, including by allowing new wholesalers to enter the market.

These are important aspects to be considered by pharmaceutical companies when thinking of minimizing the risks of competition concerns.

To sum up, promotion of innovation in pharmaceutical sector strengthens the overall competitiveness of the EU market. In addition, it is obvious that the Commission is interested in the protection and promotion of this essential sector of the European economy, as proved in documents and proposals issued by it to this effect. In this regard, the overall picture around the restrictions on parallel trade by pharmaceutical companies provides the room for justification within the EU competition rules. The trend from the Courts is that more economic analysis and the economic arguments about the side effects of parallel trade in long run are taken into account. This shows that the CJEU's doors would open slowly and slightly for pharmaceutical companies argumentatively prayers, however only with high scrutiny and cautious from the CJEU side.

It means that when pharmaceutical company would prove efficiency gains and positive effects on consumer welfare of restraints on parallel trade, these actions would survive the application of competition rules. Moreover, taking into account consumer welfare considerations and linking it to the well being of people, would enhance the aim of internal market from a different angle; and by doing so the possible controversy between free movement of goods and restrictions on parallel trade would be overcome in particular cases. However this does not leads to a general approach of exempting the whole pharmaceutical sector, rather it is possible to justify only on a case by case basis.

Finally, one is clear that the CJEU seems more comfortable to take economic considerations into account and abandon pure legal approach in pharmaceutical industry. Therefore, it seems that interesting times lie ahead in terms of competition policy enforcement and advocacy in the pharmaceutical sector. At the very least, the Commission's past focus on intra-brand competition may be expected to be complemented by a more nuanced multi-faceted approach aimed at inter-brand competition to deliver enhanced consumer welfare to patients throughout the EU.

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