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Limiting Parallel Trade of Drugs and Article 82
What Role for Innovation and Efficiencies as Justifications
after the ECJ Decision in *Sot. Lelos Kai Sia*?

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Abstract

With its decision in *Sot. Lelos Kai Sia*, the ECJ brought a bit of clarity into the relationship between Article 82 and unilateral behaviours aimed at limiting parallel trade of drugs. The ECJ held that a dominant pharmaceutical company, which refuses to fully supply extraordinary orders of its existing wholesalers, does not breach Article 82 since this refusal can be seen as a reasonable and proportionate measure to protect its legitimate commercial interests. In saying this, the ECJ based its reasoning on the market imperfections characterizing the pharmaceutical sector, namely the state intervention in the price setting and the moral and legal obligation for the pharmaceutical companies to appropriately and continuously supply the domestic markets. Other justifications put forward by the contested pharmaceutical company such as the need to protect its capacity and incentive to invest in R&D or the existence of efficiencies were not taken into consideration at all. While the solution proposed in *Sot. Lelos Kai Sia* seems to have pleased all the interested parties, some doubts about its consistency with the new “effects-based” approach promoted by the Commission in the application of Article 82 remain. This paper will therefore discuss this solution in order to verify whether it can be considered a solid precedent or rather a “shortcut” taken by the ECJ to avoid complex economic analysis which it was still not ready to embark on.

Keywords

Consumer Welfare

Effects-based Approach

Innovation

Objective justifications

Efficiency defence

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List of Abbreviations

AG	Advocate General
CFI	Court of First Instance
CMLRew	Common Market Law Review
EAEPCC	European Association of Euro- Pharmaceutical Companies
EC	European Community
E.C.R.	European Court Reports
E.C.L.R.	European Competition Law Review
ECJ	European Court of Justice
EFPIA	European Federation of Pharmaceutical Industries and Associations
E.L.Rev	European Law Review
EU	European Union
FDA	Food and Drug Administration
GSK	GlaxoSmithKline
NCAAs	National Competition Authorities
NHS	National Healthcare Systems
O.J.	Official Journal
R&D	Research and Development
US	United States of America
W.Comp	World Competition

1 Introduction

The European Courts have always supported parallel trade amongst Member States given its capability of lowering prices and giving more choice to final consumers, thereby enhancing consumer welfare.

However, this assumption has been recently questioned within the pharmaceutical sector. It has been argued that, given the specific features of this sector, parallel trade of drugs is not a consumer welfare enhancing tool. In particular, besides the positive effects parallel trade can generate in the short run in importing countries, it produces negative effects, both in the short and in the long run, whose magnitude is much larger than any positive effect.

This theoretical debate has obviously had an impact on the relationship between antitrust rules and practices carried out by pharmaceutical companies with the aim to limit parallel trade.

In *GlaxoSmithKline Services*¹, the CFI, diverging from the previous case law of the ECJ in *Sandoz*², held that a clause aimed at limiting parallel trade of drugs cannot be considered a restriction of competition *by object* under Article 81. In fact, given the strong state intervention in the price setting, it cannot be presumed that parallel trade tends to reduce drug prices in importing countries and, consequently, increase consumer welfare³.

This ruling represented a substantial novelty in the Article 81 panorama, because for the first time the CFI questioned the presumption that parallel trade has always positive effects for consumer welfare. As known, the decision was appealed by both the Commission and GSK and the case is now pending before the ECJ⁴.

The same issue has been proposed with respect to the application of Article 82⁵. The issue was to understand if and to what extent a dominant pharmaceutical company can justify its

¹ Case T-168/01, *GlaxoSmithKline Services v. Commission*, [2006] ECR II-2969. For a comment of this ruling, see V. JUNOD, “An End to Parallel Imports of Medicines? Comments on the Judgement of the Court of First Instance in *GlaxoWellcome*”, (2007), 30(2) W.Comp, p.291.

² Case C-277/87, *Sandoz Prodotti Farmaceutici v. Commission*, [1990] ECR I-45.

³ However, the CFI found that the clause had the effect of restricting competition. See *GlaxoSmithKline Services v. Commission*, supra note 1.

⁴ Case C-501/06P, *GlaxoSmithKline Services v. Commission* (pending).

⁵ A shift of the Commission, NCAs and national courts towards Article 82 was caused by the Commission's *debacle* in the Adalat case, where the European Courts held that a modification of the supply

unilateral conducts aimed at limiting parallel trade of drugs putting forward the specificities of the pharmaceutical sector and efficiency considerations.

The issue was brought to the attention of the ECJ by two subsequent requests for a preliminary ruling made respectively by the Greek Competition Authority and the Greek Court of Appeal of Athens. Before the adoption of the final decision by the ECJ, this issue was the object of two different Advocate Generals' opinions, Jacobs⁶ and Ruiz-Jarabo Colomer⁷, who proposed opposite solutions.

With its ruling in *Sot. Lelos Kai Sia*⁸, the ECJ tried to bring a bit of clarity to this field. The ECJ held that a dominant pharmaceutical company can take *reasonable* and *proportionate* measures to protect its legitimate commercial interest. In this perspective, a refusal to supply *extraordinary* orders of *existing* wholesalers is objectively justified.

This ruling was felt as a victory by either the pharmaceutical companies or the parallel distributors⁹. Pharmaceutical companies interpreted the ruling as a green light for their supply-quota policies, whereas parallel distributors considered the ruling as firm recognition of the legitimacy of the parallel trade of drugs.

The aim of this paper is not to analyse who, between the above parties, was right in welcoming the ruling of ECJ, but rather to discuss the rule adopted by the ECJ with respect to the “objective justification”.

In the case at stake, GSK claimed that its conduct was justified taking into account (i) market imperfections of the pharmaceutical sector (in particular, state intervention in price setting and

policy aimed at stopping parallel trade does not constitute an agreement or concerted practice pursuant to Article 81. See respectively: Commission Decision of 10 January 1996, *Adalat*, [1996] O.J. L210/01; Case T-41/96, *Bayer v. Commission*, [2000], ECR II-3383; Case C-02/01P, *BAI and Commission v. Bayer*, [2004] ECR I-23.

⁶ Opinion of AG Jacobs, Case C-53/03, *Synetairismos Farmakopoiion Aitolias & Akarnanias (Syfait) and Others v. Glaxowellcome AVEE*, [2005] ECR I-4609, at para 74.

⁷ Opinion of AG Ruiz-Jarabo Colomer of 1 April 2008, Joined Cases C-468/06 to C-478-/06, *Sot. Lelos kai Sia EE and others v. GlaxoSmithKline AVEE Farmakeftikon Proionton* (not yet reported).

⁸ Judgement of 16 September 2008, Joined Cases C-468/06 to C-478/06, *Sot. Lelos Kai Sia EE and others v. GlaxoSmithKline AVEE Farmakeftikon Proionton* (not yet reported).

⁹ See press releases of 16 September 2008 of the EFPIA, available at <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=5383> and of the EAEPCC, available at http://www.eaepc.org/news_and_press/news.php?n=3&id=380 (last access on 25 April 2009).

duty to supply), (ii) the serious risks for its capacity and incentive to innovate arising from parallel trade and (iii) efficiency considerations (no “net harm” for consumers).

Neither of the justifications under point (ii) and (iii) were taken into consideration by the ECJ. These justifications appear more in line with the new effects-based approach promoted by the Commission in the application of Article 82 but they require a complex economic analysis.

This paper will therefore discuss the solution proposed in *Sot. Lelos Kai Sia*, in order to verify whether it can be considered a solid precedent or rather a “shortcut” took by the ECJ to avoid complex economic analysis which it was not ready to embark on.

The paper is structured in six chapters. After the brief introduction constituting the first chapter, the second chapter will describe the principal specific features of the pharmaceutical sector and parallel trade of drugs, including an overview of the positive and negative effects of the latter on consumer welfare, both in the short and in the long run. The third chapter will be dedicated to an analysis of the European case law on “objective justifications” as well as of the paragraphs of the recent Guidance on Article 82¹⁰ (“Guidance”) dedicated to this aspect. The fourth chapter will then verify how the justifications based on the risk to innovation and efficiency considerations have been taken into account in the opinions of AG Jacobs and AG Ruiz-Jarabo Colomer, and in the recent ruling of the ECJ. The fifth chapter will discuss whether risk to innovation and efficiency considerations can still be used by the pharmaceutical companies to justify their *prima facie* abusive conducts. After having demonstrated this possibility, the paper will try to provide the lector with some insights on how these arguments should be put forward by the pharmaceutical companies and/or taken into consideration by the courts and the competition authorities. The sixth chapter will contain the conclusions.

¹⁰ Commission communication on guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, [2009] O.J. C45/7.

2 Parallel trade and pharmaceutical sector

This chapter will first contain a general overview of parallel trade of drugs (para. 2.1). The remaining three paragraphs will instead be dedicated to discuss, also from a critical point of view, the specificities of pharmaceutical sector (para. 2.2) and parallel trade of drugs (para. 2.3), as well as all the possible (positive and negative) effects of parallel trade on consumer welfare, both in the short and in the long run (para 2.4).

2.1 General overview of parallel trade of drugs

Parallel trade is a lawful form of trade in goods between Member States. It is called “parallel” because it takes place in parallel with the distribution network that the manufacturers have established in a given Member State, but it concerns products which are similar to the ones marketed by the official distribution networks.

In Europe, parallel trade of drugs¹¹ is based on the freedom of movement of goods, pursuant to Articles 28 and 30 and on the “regional exhaustion doctrine”. On this basis, once a drug is placed in the market of one Member State by the right holder or with its consent, the latter cannot oppose that the same drug be exported in another Member State¹².

The figures of parallel trade of drugs are quite significant. According to data provided by the EFPIA, parallel trade was estimated to amount to € 4,100 million (value at ex-factory prices) in 2005, reaching market share between 10-15% in Denmark, Sweden, the Netherlands and UK¹³.

Parallel trade of drugs have been contrasted by pharmaceutical companies. Parallel trade is a form of arbitrage and, as such, it reduces the revenues earned by the pharmaceutical

¹¹ The terms “drugs” and “pharmaceutical products” will be used to mean “patented prescription medicines”. The possible parallel trade of over-the-counter medicines (“OTC”) or generics will not be analysed in this paper.

¹² The regional exhaustion doctrine was elaborated for the first time by the ECJ in Case 78/70, *Deutsche Grammophon v. Metro*, [1971] ECR 487.

¹³ The Pharmaceutical Industry in Figures, 2007 update, available at: <http://212.3.246.100/Objects/2/Files/infigures2007.pdf> (last access on 11 April 2009), p.4.

companies in importing countries. There is therefore an interest for the pharmaceutical companies to stop or at least limit parallel trade in order to reduce the above losses.

In order to reach this goal, the pharmaceutical companies have adopted different systems, such as (i) dual pricing systems, (ii) supply-quota systems and (iii) refusals to supply towards those wholesalers expressing their intention to engage in parallel trade.

As conducts carried out by *undertakings*, they must be consistent with the provisions contained in Articles 81 and 82.

In other sectors, conducts aimed at limiting parallel trade have always been strongly condemned by the European Courts¹⁴, based on the grounds that parallel trade encourages trade and reinforces competition¹⁵.

The relationship between parallel trade and Article 82, however, seems to have *unique* features in the pharmaceutical sector, because of some specific characteristics of the latter¹⁶.

Hereinafter, the lector will be provided with some insights on the alleged specificities of the pharmaceutical sector, as well as on the impact of parallel trade for consumer welfare.

2.2 *Specific features of the pharmaceutical sector*

2.2.1 **The role of innovation and the cost structure**

The pharmaceutical industry is an R&D-driven sector where companies strongly compete on innovation in order to create new drugs, rather than on prices.

Large amount of time and investments are needed in the R&D of a new drug to be marketed. In a report commissioned by the DG Enterprises and Industries it is said that an R&D project for a new drug is likely to last 8-12 years, with a cost in the range of \$ 350-650 million¹⁷.

¹⁴ Case C-26/75, *General Motors Continental v. Commission*, [1975] ECR 1367, at 12; Case C-226/84, *British Leyland v. Commission*, [1986] ECR 3263, at 24.

¹⁵ Case C-373/90, *X*, [1992] ECR I-131, at 12.

¹⁶ This consideration applies also to the relationship between parallel trade and Article 81, but, as the title suggests, this paper will be mainly focused on Article 82 cases.

According to data provided by EFPIA¹⁸, the pharmaceutical industry is the sector with the highest ratio of R&D investment to net sales at worldwide level, which amounts to 14.9%.

While R&D expenditure is a very high cost that is sunk¹⁹, the variable cost to produce a drug once developed is comparatively very low.

The specific feature of any R&D expenditure is that it is a global joint cost, that means a cost which is the same regardless of the number of consumers or countries served. This is relevant in the price setting, because joint global cost as R&D expenditure cannot be allocated to specific products in specific countries. Although utilities such as electricity, gas or telephone have high joint sunk capital costs, here the capital is country specific and it obviously must be paid by local consumers. Conversely, in the pharmaceutical sector, most of the capital is intangible R&D capital which is not specific to the country using regulation to influence the price²⁰.

From the above, one can infer two consequences. First, it is rational for a pharmaceutical company to supply its drugs in Member States where the prices are above country-specific average variable costs. Second, the mere fact that a product is marketed in one Member State at a given price which is above the country-specific average variable cost but below the average total cost does not mean that a pharmaceutical company could recoup its total costs if that price was generally applied.

2.2.2 Drug price setting

¹⁷ A. GAMBARDELLA, L. ORSENIGO, F. PAMMOLLI, “Global competitiveness in pharmaceuticals”, November 2000, available at: http://ec.europa.eu/enterprise/library/enterprise-papers/pdf/enterprise_paper_01_2001.pdf (last access on 11 April 2009).

¹⁸ The Pharmaceutical Industry in Figures, supra note 13, p.7.

¹⁹ A sunk cost is an expenditure that cannot be recovered. See J. M. PERLOFF, *Microeconomics*, 5th edition, Pearson Addison Wesley, London, 2007, p.185.

²⁰ P. M. DANZON, “The Economics of Parallel Trade”, (1998), 13(3) *Pharmaeconomics*, p.297.

As to the pricing, the Community intervention is minimal. Member States are only obliged to respect the “effectiveness” criteria contained in the “Transparency Directive”²¹.

Apart from this, Member States still retain an exclusive competence as to the pricing of pharmaceutical products²². Some Member States have decided to fix drug prices unilaterally or through negotiations with pharmaceutical companies, whereas other Member States leave the pharmaceutical companies fix the prices²³.

In deciding whether intervene or the extent of such intervention, Member States pursue different public policies.

Some Member States intervene in order to protect the budgets of the NHS, which cover most of the costs of such products, or to assure that everybody can afford to buy vital products such as drugs²⁴. The result is in any case a strong public intervention aimed at lowering drug prices.

Other Member States are instead willing to allow pharmaceutical companies to sell at higher prices, in order to ensure sufficient returns that may constitute an incentive for the R&D of new drugs²⁵.

2.2.2.1 State intervention as main reason for price differential

The result of these different policies is that prices of drugs significantly differ across the EU, with lower prices in the southern countries such as Spain, Portugal, Italy, France and Greece,

²¹ Council Directive 89/105/EEC of 21 December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, [1999] O.J. L40/8.

²² The Commission has recognized that “establishing an appropriate level of price across the Community would prove extremely difficult”. See Commission Communication on the Single Market in Pharmaceuticals, 25 November 1998, COM(98) 588 final, available at: http://ec.europa.eu/enterprise/library/lib-regulation/doc/com-98-588_en.pdf (last access on 11 April 2009), p.11.

²³ Only UK and Germany do not control directly drug prices even though they provide some indirect instruments of price control. See CRA International, “Innovation in the pharmaceutical sector”, 8 November 2004, available at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2004/nov/eu_pharma_innovation_25-11-04.pdf (last access on 22 April 2009), p.84, note 70.

²⁴ There is still a significant difference amongst Member States as to the income per capita of the population. See GDP per capita, consumption per capita and comparative price levels in Europe, 8 December 2008, available at: http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-SF-08-112/EN/KS-SF-08-112-EN.PDF (last access on 11 April 2009).

²⁵ P. REY, J. S. VENIT, “Parallel Trade and Pharmaceuticals: A policy in Search of itself”, (2004), 29 E.L.Rev., p.162.

and higher prices in the northern countries such as Germany, UK, the Netherlands and Scandinavia²⁶.

It would follow that “wholesale prices differential for patented drugs mainly reflect differences in the way countries regulate their pharmaceutical markets and how prices are determined in negotiations between governments and industry”²⁷.

In all Member States, the total (or at least the greater part of) cost of the drugs is borne by the NHS, usually through a reimbursement system, and not by the patients. Therefore, from an economic point of view, the relevant customer is the government rather than the single patients²⁸.

The Governments thus hold a strong *monopsony power* that is used to force prices down to the variable cost of supplying their own countries, leaving to other countries the onus to pay the joint costs for R&D. At the same time, the pharmaceutical companies have no incentive to interrupt in the short run the supply of drugs as long as price covers the country-specific variable cost²⁹.

2.2.2.2 State intervention as one of the reasons for price differential

From an economic standpoint, the theory of state intervention as sole (or mainly) factor causing the price differential amongst Member States is not unquestionable.

According to the economic theory, the factors influencing the price of drugs are manifold.

²⁶ For a comparison of 19 pharmaceutical products in 14 European countries, see P. KANAVOS *et al.*, “The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis”, January 2004, available at: <http://212.3.246.100/Objects/2/Files/LSEstudyparalleltrade2003.pdf> (last access on 11 April 2009), p.142.

²⁷ Oxera, “Shades of grey: arguments for and against parallel trade in pharmaceuticals”, October 2008, available at: http://www.oxera.com/cmsDocuments/Agenda_October08/Parallel%20trade%20in%20pharmaceuticals.pdf (last access on 11 April 2009), p.3.

²⁸ P. REY, J. S. VENIT, *supra* note 25, p.161.

²⁹ P. M. DANZON, *supra* note 20, p.296. Given the global nature of R&D spend, variable cost and avoidable cost would be almost the same.

First, the price differential is often due to the variation in the exchange rate between countries that is exploited by the parallel traders³⁰.

Second, costumers located in different countries (or, more precisely, Governments) may have a different willing to pay. This can be particularly true if one considers the different income per capita characterizing the various Member States, which has been further increased with the enlargement and the accession to the EU of 10 new Member States³¹. Therefore, a significant price differential amongst Member States could occur even in the absence of any state intervention and just a result of the different price elasticity of the demand.

Third, one should take into consideration the fact that the regimes of intellectual property vary significantly, so that a patent still in force in one Member State could instead be expired in another Member State. It follows that the entry of competition from generics may exercise a downward price pressure in some countries and not in others³².

Fourth, the pharmaceutical companies enjoy a significant decree of strength in the market that can be used to counteract the monopsony power of the Governments.

In this perspective, therefore, the state intervention should be seen as one of the factors influencing the price differential and not the only or mainly one.

2.2.3 Public service obligation

Another specific feature of the pharmaceutical sector is the so-called public service obligation.

In this respect, Article 81 of Directive 2001/83³³ states the following: “the holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in that Member State shall, within the limits of their

³⁰ See *ex multis* C. E. BARFIELD, MARK A. GROOMBRIDGE, “Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy”, (2006), 10 *Fordham Intellectual Property, Media, and Entertainment Law Journal*, p.246.

³¹ See previous note 24.

³² C. E. BARFIELD, MARK A. GROOMBRIDGE, *supra* note 30, p.246

³³ Council Directive 2001/83/EC of 6 November 2001, on the Community code relating to medicinal products for human use, [2001] O.J. L311/67.

responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of the patients in the Member State in question are covered”.

Besides this general obligation under EC law, pharmaceutical companies and wholesalers are subject to additional duties under national law aimed at guarantying the constant supply of drugs.

2.3 Specific features of parallel trade of drugs

In principle, parallel trade leads (i) to price equalisation across countries, thus resulting in more efficient market operations and (ii) to increased price competition in importing countries, thus reducing overall drug prices and, consequently, benefiting payers and patients. These assumptions, which generally apply in the various sectors, have been heavily contested when applied within the pharmaceutical sector.

2.3.1 Price equalisation

Price equalisation is welfare enhancing when lower prices in the exporting countries reflect real cost of production due to either lower input costs or superior efficiency³⁴.

The input costs for drugs are almost the same in all Member States. The production techniques are uniform across Europe, as the pharmaceutical production has to be consistent with GMP (“Good Manufacturing Practice”) everywhere. The only possible saving is the lower labour cost of packaging and processing drugs, which, however, represents only a minor part of the total cost and may not justify any significant price differential³⁵.

Therefore, some Member States have lower prices for drugs not because the production is more efficient or the inputs are cheaper but because of the strong price regulation. In light of the above, it has been argued that “because parallel trade exploits regulated price differences

³⁴ P. M. DANZON, *supra* note 20, p.299.

³⁵ *Ibid.*

that do not reflect real cost differences, such trade can actually increase social costs because of additional transportation and administrative costs”³⁶.

2.3.2 Benefits for payers and patients

As to the concrete benefit of parallel trade for payers and patients, the economic literature is divided into two main groups.

2.3.2.1 Only minimal benefits

Two studies well represent this group: a report conduct by the London School of Economics in 2004³⁷ (“2004 LSE Report”) and a paper written by Kanavos and Costa-Font in 2005³⁸. Both studies reach similar conclusions.

First, benefits for patients and NHS are minimal. In 2002 and taking into account 6 countries normally considered importing countries³⁹, the savings amounted to € 100 millions or to 1,8% of total brand retail sales. On the contrary, the financial benefits for parallel distributors were € 648.4 million, whereas the total impact of parallel trade for the pharmaceutical industry was estimated between € 1.9 billion and € 3.8 billion. The ratio of gross revenues to parallel distributors over savings to NHS is 6.48⁴⁰.

Second, parallel trade does not even result in any price competition leading to an overall price reduction in the long term, neither (i) between parallel distributors nor (ii) between original manufactures and parallel distributors. Empirical analysis show that the difference between the highest and lowest price made by parallel distributors does not exceed 7% and that there is a small price difference between locally sourced drugs and imported drugs, especially in countries such as Germany, the Netherlands and UK⁴¹.

³⁶ Ibid. To describe this process, Kanavos used the wording “regulation-derived arbitrage”. See P. KANAVOS, J. COSTA-FONT, “Pharmaceutical Parallel Trade in Europe: Stakeholder and Competition Effects”, (2005), *Economic Policy*, p.755.

³⁷ P. KANAVOS *et al*, supra note 26.

³⁸ P. KANAVOS, J. COSTA-FONT, supra note 36.

³⁹ Norway, Germany, Sweden, Denmark, UK and the Netherlands.

⁴⁰ P. KANAVOS, J. COSTA-FONT, supra note 36, pp.773-775.

⁴¹ Ibid, pp.775-779.

In light of the above, it is concluded that parallel trade of drugs mainly benefit parallel distributors rather than patients and NHS.

2.3.2.2 Significant benefits

Other economic studies proved that parallel trade of drugs generates significant savings for patients and NHS.

A first report was carried out by the York Health Economics Consortium in 2003 (“2003 York Report”). According to this report, taking into account UK, Germany, Sweden, Netherlands and Denmark, the direct savings in 2001 amounted to 635 million⁴².

A second report was then carried out by the University of Southern Denmark (“2006 USD Report”)⁴³, which tried to review the existing literature dominating the debate, in particular the 2003 York Report and the 2004 LSE Report. The 2006 USD Report argues that the methodology applied for estimating the direct savings by the 2003 York Report was the most appropriate.

The 2006 USD Report confirms the conclusion that parallel trade generates significant direct savings for patients and NHS. In Denmark, Sweden, Germany and UK these savings amounted in 2004 to € 441,5⁴⁴. In addition, 2006 USD Report demonstrated that savings represent a substantial share of the parallel import turnover, ranging from 10% in UK to 20.4% in Sweden in 2004⁴⁵.

The 2006 USD Report also finds that parallel trade does exercise competitive pressure on prices and quantifies the indirect savings generated by the parallel trade (i.e. the savings generated by the downward pressure exerted on the price of the original, directly imported products) in two specific countries, Denmark and Sweden⁴⁶.

⁴² P. WEST, J. MAHON, “Benefits to Payers and Patients From Parallel Trade”, May 2003, available at: <http://archives.who.int/prioritymeds/report/append/8210ParallelTradeReport.pdf>, (last access 12 April 2009), p.67.

⁴³ K. M. PEDERSEN *et al.*, “The economic impact of parallel import of pharmaceuticals”, June 2006, available at: <http://www.reducedrugprices.org/read.asp?news=298> (last access on 26 April 2009).

⁴⁴ Ibid, p.48.

⁴⁵ Ibid, p.5.

⁴⁶ Ibid, p.48.

Before the 2006 USD Report, the competitive pressure effect exercised by parallel trade had also been demonstrated in the Swedish market in the period between 1995 and 1998⁴⁷.

2.4 Effects of parallel trade on consumer welfare: short run vs. long run

Parallel trade can have positive and negative effects on consumer welfare, either in the short run or in the long run. The aim of this part is not to discuss in detail the exact magnitude of all the above effects. This would need a case-by-case analysis and goes beyond the purpose of this paper. The following part of the paper will therefore focus on the “direction” of these effects, using the most recent and authoritative economic studies.

2.4.1 Savings and lower prices for importing countries

This point has been already discussed in the previous para. 2.3.2. It suffices to remember how the economists have thus far given different answers with respect to the extent of these effects.

2.4.2 Instabilities in the supply chain of exporting countries

Parallel trade may harm consumers in exporting countries by creating instabilities in the supply chain⁴⁸.

Evidence suggests that parallel trade can result in shortages in drugs that are exported intensively. This shortage has been documented in Greece⁴⁹, where the parallel export in 2002 amounted to 22% of its total market. There also evidences of shortages in Spain and in France. In Greece and in Spain, in order to avoid other shortages, the regulator has introduced the obligation for the wholesalers to declare the destination of the drugs they acquire⁵⁰.

⁴⁷ M. GANSLANDT, K. E. MASKUS, “Parallel imports of pharmaceutical products in the European Union”, (2001), *World Bank Policy Research Working Paper* no. 2630.

⁴⁸ A. COSCELLI, G. EDWARDS and A. OVERD, “Parallel Trade in Pharmaceuticals: More Harm than Good?”, (2008), 8 E.C.L.R., p.492.

⁴⁹ TO VIMA, (2002), *Pharmaceutical Product Shortages in the Greek Market, 2001–2002*, 10 April 2002, based on a communication with the National Pharmacists’ Association.

⁵⁰ P. KANAVOS, J. COSTA-FONT, *supra* note 36, p.791.

2.4.3 Delay in the launch of new drugs in exporting countries

Parallel trade may also harm consumers in the exporting countries by contributing to delay the supply of new drugs⁵¹.

Some pharmaceutical companies have admitted that they prefer to withhold or delay the launch of new drugs in countries traditionally having low prices rather than accept prices which favour the parallel trade and can erode their revenues in the high price countries, especially if the latter have larger markets⁵².

A 2005 study demonstrated that countries that tend to lower the price of drugs through regulation have fewer products launched and longer delays for those products already launched in other countries. By way of example, the authors note that of the 29 new chemical entities approved by the EMEA since 1996, 23 were launched in Sweden, compared to only 5 in Portugal, 8 in Italy, 12 in Greece and Spain⁵³.

2.4.4 Lower R&D spending (i.e. the causal link)

2.4.4.1 Existence of a causal link

As already seen, the pharmaceutical sector is an R&D-driven sector. The decision on how much invest in R&D depends on various competitive conditions, but the most important ones are (i) the funds currently available and (ii) the return that a successful investment is expected to generate⁵⁴.

The availability of current funds is particularly crucial in the pharmaceutical sector because R&D is mainly financed through internal sources. Pharmaceutical industry is characterized by high product failure rate and high product liability. These two circumstances, together with the information asymmetry affecting the outside lenders, which do not have the ability to actually assess the value of a pharmaceutical project, make the external financing really rare⁵⁵.

⁵¹ A. COSCELLI, G. EDWARDS and A. OVERD, *supra* note 48, p.492.

⁵² P. M. DANZON, *supra* note 20, p.300.

⁵³ See P. M. DANZON, Y. R. WANG, L. WANG, "The Impact of price Regulation on the Launch of new drugs – Evidence from Twenty-Five Major Markets in the 1990s", (2005), 14 *Health Economics*, p.269.

⁵⁴ P. REY, J. S. VENIT, *supra* note 25, p.163. The authors acknowledge that this decision can also be influenced by other factors, such as regulatory measures or fiscal incentives.

⁵⁵ *Ibid.*

Expected future revenues are also important because they represent an incentive to invest in R&D.

The relationship between (current and expected) revenues and R&D has been deeply investigated under a theoretical point of view⁵⁶. Some studies have also conducted empirical analysis concerning the relationship between price control measures and R&D.

A 2002 study⁵⁷ found that price control measures negatively affect innovation. In particular, it analyses the effects of Medicaid rebates for drugs⁵⁸ on innovation in the US market. The analysis shows that such rebates are likely to decrease the number of new drug applications filed each year before the FDA by 1.24 and the annual number of new drug applications approved by the FDA by 4.14. Thus, “the opportunity costs of the Medicaid rebates in the US are more than 4 newly approved drugs per year”⁵⁹.

A similar empirical analysis was also conducted for some European countries. The analysis found that a reduction of drug prices in 2004 by 1% led to a fall in R&D investment of 0.68%⁶⁰.

This reasoning is then extended to parallel trade, which, like any state measure reducing drug prices, can be expected to reduce the current and expected revenues and, consequently, the ability and incentive of pharmaceutical companies to invest in R&D⁶¹.

As concluded in a recent paper “[T]he extent to which lower profits translate into lower R&D spend will differ across companies and will be one of the key empirical issues to analyse in

⁵⁶ See the literature quoted in C. DESOGUS, “Parallel Trade and Pharmaceutical R&D: The Pitfalls of the Rule of the Reason”, (2008), 11 E.C.L.R., p.663, note 91.

⁵⁷ J. L. TROYER, A. V. KRASNIKOV, “The effect of price regulation on innovation in the pharmaceutical industry”, (2002), 18(4) *Journal of Applied Business Research*, pp.87-96.

⁵⁸ The US Medicaid programme was established in 1990 and includes two key rebate provisions: (i) a most-favoured-customer clause for prices of drugs supplied to Medicaid recipients and (ii) a discount of at least 15.1 percent on the wholesale price of branded medicinal products. See CRA International, supra note 23, p.83, note 67.

⁵⁹ CRA International, supra note 23, p.83.

⁶⁰ US Department of Health and Human Services (1994), discussed in J. L. TROYER, A. V. KRASNIKOV, supra note 57, p.88.

⁶¹ CRA International, supra note 23, pp.84-85.

any specific case, but the empirical economic literature strongly suggests that lower profits lead to reduced R&D spending”⁶².

2.4.4.2 Absence of a causal link

Other authors contest this causal link, or at least they argue that it is very hard to demonstrate and depending on various factors.

First, it has been argued that it is not true that the total appropriation of all possible returns does necessarily result in more innovation⁶³. The effect of parallel trade on R&D depends, *inter alia*, on the shape of the innovation production function over the research and development cost levels. Assuming diminishing return to scale, there will cost levels at which the marginal productivity is low and at which the effect of reduced R&D costs on innovation will be negligible. On the contrary, there will be cost levels at which the effect of reduced R&D costs on innovation will be significant⁶⁴.

In addition, given the long period necessary to develop a new drug (8-12 years) and the regulatory environment where the pharmaceutical companies operate, the factors causing a reduction of returns may be manifold. For instance, the “domino effect” of reference price system is capable of reducing the returns not only in Europe but globally. It follows that the parallel trade cannot be the main factor, but one of the factors capable of having an incremental effect on the returns⁶⁵.

The conclusion is that, given the features of the pharmaceutical sector, the role of regulation, the time lag between the factor reducing the returns (i.e., parallel trade) and the effect on innovation, proving, in an empirical way, the existence of a convincing causal link is almost unfeasible⁶⁶.

⁶² See A. COSCELLI, G. EDWARDS and A. OVERD, *supra* note 48, p.491.

⁶³ C. HUMPE, C. RITTER, “Property, Intellectual Property and Free Riding, (2005), 83 *Texas Law Review*, p.1031-1057.

⁶⁴ C. DESOGUS, *supra* note 56, p.660; K. M. PEDERSEN *et al*, *supra* note 43, p.16.

⁶⁵ C. DESOGUS, ”Il commercio parallelo disincentiva la ricerca farmaceutica?”, (2008), 4 *Il Diritto Industriale*, p.344.

⁶⁶ *Ibid.*

2.4.5 Reductions in R&D likely leads to reductions in consumer welfare

It has been argued that a reduction in R&D spends will likely lead to significant reduction in consumer welfare⁶⁷. To explain this proposition, it is used the following example. Let's assume that, because of parallel trade, the revenues of a manufacture fall by € 50 million, which is also the amount of the gains for consumers⁶⁸ arising from parallel trade⁶⁹.

Assuming a strong link between revenues and R&D, and since R&D investments are typically around 15% of sales, they assume that R&D spending to be € 7.5 million lower than it would be lacking parallel trade. Taking a conservative estimate based on a 2004 paper of Lichtenberg⁷⁰ according to which € 1,000 in R&D investments generates one additional life-year⁷¹, the impact of parallel imports on the R&D budget of a company comes potentially at the expense of € 7,500 life-years.

Finally, considering that one life-year is worth approximately € 75,000⁷², the cost for consumers would more than € 500 million, thus much larger than the gains obtained consumers, which, in the example, amounted to € 50 million.

The conclusion is that parallel trade is likely to produce in the long run a negative effect on the consumer welfare which is much larger than any other positive effects, either in the short or in the long run⁷³.

⁶⁷ A. COSCELLI, G. EDWARDS and A. OVERD, *supra* note 48, pp.491-492.

⁶⁸ The terms "consumers" includes the NHS.

⁶⁹ As noted by the authors, this estimation is conservative because the gains stemming from parallel trade are never completely absorbed by the consumers but rather split amongst them, the pharmacies and the parallel distributors.

⁷⁰ F. R. LICHTENBERG, "Sources of US Longevity Increase, 1960-2001", (2004), 44(3) *Quarterly Review of Economics and Finance*, p.369.

⁷¹ According to the authors, this finding has been relied upon by a number of subsequent studies as a measure of the productivity of pharmaceutical R&D investments.

⁷² According to the authors, the estimate is based on a review of the economic literature on the value of life-years.

⁷³ However, the same authors expressively acknowledge the weaknesses of this proposition. See A. COSCELLI, G. EDWARDS and A. OVERD, *supra* note 48, p.492.

3 Justifications of prima face abusive conducts

Unlike Article 81, Article 82 could appear drafted in terms of an absolute prohibition, without exceptions being provided. Notwithstanding the above, the Commission and the European Courts have developed an analysis of Article 82 based on the notion of “objective justification” which has brought about some flexibility in the application of Article 82⁷⁴. According to this approach, a conduct, which in a *first-step* analysis is considered abusive, could in a *second-step* analysis escape from the scope of application of Article 82 because “objectively justified”⁷⁵. This process has taken place on a case-by-case analysis, without providing a clear and systematic picture of the circumstances which objectively justify otherwise abusive conducts.

A first clarification of the law on this point was contained in the Discussion Paper on the Application of Article 82 to exclusionary abuses (“Discussion Paper”)⁷⁶ and is now crystallized in the Guidance. The Guidance has introduced, for the first time, an “efficiency defence”⁷⁷ to be applied on Article 82 cases. In addition, it has reaffirmed the “objective justification” category promoted by the European Courts, providing, however, a regime which, in the author’s opinion, does not appear perfectly in line with the relevant case law.

The following paragraph will discuss the relevant European case law (para. 3.1) and the approach promoted by the Commission (para. 3.2).

3.1 Objective justifications under the European case law

⁷⁴ A. ALBORS-LLORENS, “The Role of Objective Justification and Efficiencies in the Application of Article 82 EC”, (2007), 44 CMLRev, p.1727.

⁷⁵ For a criticism to the two-step approach, see P.J. LOEWENTHAL, “The Defence of “Objective Justification” in the Application of Article 82”, (2005), 28(4) W.Comp, p.459; Opinion of AG Kirschner, Case T-51/89, *Tetra Pak Rausing SA v. Commission*, [1990] ECR II-309, at 21; Opinion of AG Jacobs, *supra* note 6, at 72.

⁷⁶ DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses, December 2005, available at: <http://ec.europa.eu/competition/antitrust/art82/discpaper2005.pdf> (last access on 13 April 2009), p.24.

⁷⁷ Please note that while the Discussion Paper contained the wording “efficiency defence”, the same has been omitted in the Guidance, which only refers to “efficiencies” without using the term “defence”.

The analysis of the European case law suggests two different lines for the justification of otherwise abusive conducts⁷⁸.

First, a dominant company is entitled to invoke the protection of its “legitimate commercial interests” as justification of its conducts. Acting to *meet competition* has been the most widely used justification within this category⁷⁹.

Second, a dominant company may argue that its conduct is objectively necessary due to some *external causes*. For instance, a shortage of supply can be invoked to justify a refusal to supply or public health or safety considerations to validate a tying agreement⁸⁰.

In addition, in one (but isolated) case the CFI seemed to pave the way for an efficiency defence.

3.1.1 Legitimate commercial interest

In *United Brands*⁸¹, the ECJ held for the first time that the protection of a legitimate commercial interest could be invoked as justification for an otherwise abusive conduct.

The notion of legitimate commercial interest is broad. Also the interest to protect the capacity to innovate and invest in R&D might be a legitimate commercial interest. This has been indirectly confirmed by the CFI in *Microsoft*, where it found that “Microsoft [...] did not sufficiently establish that if it were required to disclose the interoperability information that would have a significant negative impact on its incentive to innovate”⁸² and admitted in principle in the opinion of AG Ruiz-Jarabo Colomer in *Sot. Lelos Kai Sia*⁸³.

In *United Brands*⁸⁴, the ECJ also introduced two conditions to be met.

⁷⁸ A. ALBORS-LLORENS, supra note 74, p.1746.

⁷⁹ Ibid.

⁸⁰ Ibid.

⁸¹ Case C-27/76, *United Brands Company and United Brands Continentaal BV v. Commission*, [1977] ECR 207

⁸² Case T-201/04, *Microsoft Corp.v. Commission*, [2007] ECR II-000, at 697.

⁸³ Opinion of AG Ruiz-Jarabo Colomer, supra note 7, at 99-115.

⁸⁴ *United Brands*, supra note 81.

First, the conduct of a dominant company is not justified if its real purpose is to strengthen the position of dominance and to abuse it (the so called “genuine motivation”)⁸⁵.

Second, even if a conduct is “genuinely” aimed at protecting a legitimate commercial interest, this conduct must be “proportionate” to the threat it tends to avoid. On the facts, the ECJ found that the response of United Brands was excessive and, consequently, not justified. Unlike the approach taken in the internal market cases⁸⁶, the ECJ did not actually specify the different steps and how to apply the proportionality test, nor further guidance on this aspect have been provided in subsequent rulings⁸⁷.

Finally, it is noteworthy to clarify that the “legitimate commercial interest” justification does not contain a “balancing test”.

According to some commentators⁸⁸, the Commission tended to lay down an “incentives balance test” in the Microsoft case⁸⁹, where, in order to assess the objective justification put forward by Microsoft, it would have carried out a balance between, on the one hand, the negative effects that an obligation to supply would have had on Microsoft’s incentives to innovate and, on the other hand, the general positive effects on innovation that the same obligation would have had on the market as a whole. Since in the balance the latter effects prevailed, the Commission would have considered the refusal of Microsoft not objectively justified.

The introduction of such a new test within the “legitimate commercial interest” justification was also contested by Microsoft in the appeal before the CFI.

However, the CFI expressively rejected the argument that the Commission had used a new balance test in the application of the objective justification. According to the CFI, the

⁸⁵ Case 27/76, *supra* note 81, at 189. This condition has been confirmed in subsequent case law. See *ex multis* Case T-340/03, *France Télécom v. Commission*, [2007] ECR II-107, at 185.

⁸⁶ In the internal market cases, the European Courts have applied a test of proportionality which is two-fold: (i) a test of suitability (is the measure suitable to achieve the objective?) and (ii) a test of necessity (are there less restrictive means to reach the same results?). See C. Barnard, *The Substantive Law of the EU, The Four Freedoms*, 2nd edition, Oxford University Press, Oxford 2007, p.497.

⁸⁷ A. ALBORS-LLORENS, *supra* note 74, p.1738-1747.

⁸⁸ S. VEZZOSO, “The Incentives Balance Test in the EU Microsoft Case: A Pro-Innovation “Economic-Based” Approach?”, (2006), 27 E.C.L.R., p.382. See also: A. ALBORS-LLORENS, *supra* note 74, p.1748; P.J. LOEWENTHAL, *supra* note 75, pp.475-476.

⁸⁹ Commission Decision of 24 March 2004, *Microsoft* (not yet reported), available at <http://ec.europa.eu/competition/antitrust/cases/decisions/37792/en.pdf> (last access on 26 April 2009).

Commission rightly dismissed Microsoft's arguments not applying a balancing test but simply because the latter did not sufficiently prove that if it "were required to disclose the interoperability information that would have a significant impact on its incentives to innovate"⁹⁰.

3.1.2 Objective necessity

This second category of justification refers to situations where the cause justifying the otherwise abusive conduct is external to the dominant company.

In *BP*⁹¹ the ECJ held that a *prima facie* abusive conduct was justified because of an external and objective cause: a shortage of supplies. In *Hilti*⁹² and *Tetra Pack*⁹³ the dominant companies tried to justify their conducts using public health and safety reasons. Even though both the Commission and the CFI were in principle prepared to assess such justifications, none of them accepted these justifications on the facts.

In both cases, the arguments of the dominant companies were dismissed for lack of the first condition (i.e. the genuine motivation) and the CFI did not examine the proportionality of the conducts carried out by the dominant companies, nor gave it any guidance on how to apply it.

3.1.3 Efficiencies

*Irish Sugar*⁹⁴ represents the first case where the CFI seems to introduce an efficiency argument within the category of "objective justification", by stating that any *prima facie* abusive conduct could be objectively justified only if grounded "on criteria of economic efficiency that were consistent with the interests of consumers"⁹⁵.

However, this ruling remains an isolated case.

⁹⁰ *Microsoft*, supra note 82, at 697-711.

⁹¹ Case 77/77, *BP v. Commission*, [1978] ECR 1513.

⁹² Case T-30/89, *Hilti v. Commission*, [1991] ECR II-1439.

⁹³ Case T-83/91, *Tetra Pack International v. Commission*, [1994] ECR II-755.

⁹⁴ Case T-228/97, *Irish Sugar v. Commission*, [1999] ECR II-2969.

⁹⁵ *Ibid*, at 189.

3.1.4 Burden of proof

In *Microsoft*, the CFI gave some guidance on how to allocate the burden of proof in case of objective justification. The CFI held that, although the burden to prove the existence of circumstances constituting an infringement of Article 82 is on the Commission, it is for the dominant company concerned and not for the Commission, before the end of the administrative procedure, to raise any plea of objective justification and to support it with arguments and evidence. It then falls to the Commission, where it proposes to make a finding of an abuse of a dominant position, to demonstrate that the arguments and evidence raised cannot prevail and, accordingly, that the justification used cannot be accepted⁹⁶.

3.2 Approach promoted by the Commission

3.2.1 The Discussion Paper

The Guidance is the result of a long public consultation starting after the publication of the Discussion Paper. According to the Discussion Paper, an exclusionary conduct may escape the prohibition of Article 82 (i) in case the dominant undertaking can provide an “objective justification” for its behaviour or (ii) it can demonstrate that its conduct produces efficiencies which outweigh the negative effect on competition⁹⁷.

The Discussion Paper states that there can be two possible “objective justifications”: (i) the “objective necessity defence” and (ii) the “meeting competition defence”⁹⁸.

While the efficiencies and the “objective necessity defence” have been reaffirmed with a very similar content in the Guidance⁹⁹, the “meeting competition defence” has *bizarrely* disappeared.

The reason of this “last minute” disappearance is probably the fact that this part of the Discussion Paper was subject to a strong (and, in the author’s opinion, correct) criticism¹⁰⁰.

⁹⁶ *Microsoft*, supra note 82, at 688.

⁹⁷ Discussion Paper, supra note 76, at 77.

⁹⁸ Ibid, at 78. According to the Discussion Paper the “meeting competition defence” can be used when a dominant company is able to show that the otherwise abusive conduct is actually a loss minimising reaction to competition from others.

⁹⁹ Please note that this two defences will be discussed in the following chapter dedicated to the Guidance.

The Discussion Paper extremely narrowed the scope of application of this justification, also going well beyond what was affirmed by the European Courts.

First, instead of using the wide category of “legitimate commercial interest”, it proposed only the “meeting competition defence”, which is only a specific kind of “legitimate commercial interest” recognized by the European Courts.

Second, it affirmed that this defence was available only in relation to behaviour which otherwise would constitute a pricing abuse¹⁰¹, whereas the European Courts have applied the “legitimate commercial interest” defence also for other abuses, such as the refusal to supply in *United Brand*¹⁰².

Finally, it introduced the most stringent “proportionality test” possible. In fact, the Discussion Paper stated that in order to fulfil the proportionality test the dominant company must show that (i) the chosen conduct is a “suitable” way to achieve the legitimate aim (the so called “suitability test”), and that (ii) the conduct is “indispensable”, i.e. that the legitimate aim cannot be achieved to a similar extent by less anticompetitive alternatives and that the conduct is limited in time to the absolute minimum¹⁰³.

As seen in previous para. 3.1.1, within the “legitimate commercial interest” justification, the European Courts have never requested the “indispensability test” to be satisfied, being sufficient that the conduct is proportionate to the threat it tends to avoid.

3.2.2 The Guidance

The Guidance provides only two possible justifications for an otherwise abusive conduct.

¹⁰⁰ All the comments received by the Commission following the publication of the Discussion Paper are available at: <http://ec.europa.eu/competition/antitrust/art82/contributions.html> (last access on 13 April 2009).

¹⁰¹ Discussion Paper, supra note 76, at 81.

¹⁰² *United Brands*, supra note 81.

¹⁰³ Discussion Paper, supra note 76, at 83.

The first possible justification is the “objective necessity defence”¹⁰⁴, that means when the factors causing a *prima facie* abusive conduct are external to the dominant undertaking. By way of example of external factors, the Guidance quotes health and safety reasons related to the nature of the product in question¹⁰⁵. The Guidance then states that the “Commission will assess whether the conduct in question is indispensable and proportionate to the goal allegedly pursued by the dominant undertaking”¹⁰⁶.

The “objective necessity defence”, as formulated in the Guidance, causes some concerns.

It refers only to goals of public interest, though, as we have seen by analysing the case law, this category also contains cases of shortage of supply¹⁰⁷. In addition, it introduced an indispensability test not requested by the case law. The Guidance, unlike the Guidance paper, does not explain how this test of indispensability will be applied. However, it is likely that the Commission will follow its previous practice. In *BBI*¹⁰⁸, the Commission applied a stricter proportionality test, by stating that a response of a dominant company is not proportionate when an alternative and less restrictive measure is available to protect the same interest.

A dominant company can also justify its *prima facie* abusive conduct through efficiencies, by demonstrating that no “net harm” to consumers is likely to arise. In this context, the dominant undertaking will generally be expected to demonstrate, with a sufficient degree of probability, and on the basis of verifiable evidence, that four cumulative conditions are met.

According to para. 29 of the Guidance, a dominant company must therefore demonstrate that: (i) the efficiencies have been, or are likely to be, realised as a result of the conduct; (ii) the conduct is indispensable to the realisation of those efficiencies (there must be no less anti-competitive alternatives to the conduct that are capable of producing the same efficiencies; (iii) the likely efficiencies brought about by the conduct outweigh any likely negative effects on competition and consumer welfare in the affected markets; and (iv) the conduct does not

¹⁰⁴ The Guidance does not use this wording, which were instead used in the Discussion Paper.

¹⁰⁵ Para. 8 of the Guidance, according to the case law, states that “proof of whether conduct of this kind is objectively necessary must take into account that it is normally the task of public authorities to set and enforce public health and safety standards. It is not the task of a dominant undertaking to take steps on its own initiative to exclude products which it regards, rightly or wrongly, as dangerous or inferior to its own product”.

¹⁰⁶ Guidance, *supra* note 10, at 27-28.

¹⁰⁷ *BP*, *supra* note 91.

¹⁰⁸ Commission Decision of 29 July 1987, *Brass Band Instruments v. Boosey & Hawkes (interim measures)*, [1987] O.J. L 282/36.

eliminate effective competition, by removing all or most existing sources of actual or potential competition.

The Commission has basically introduced on Article 82 cases the same “efficiency defence” already used for Article 81 cases¹⁰⁹.

This initiative is surely welcomed because in line with the more effects-based approach that the Commission has tended to introduce with the Guidance on the application of Article 82.

However, it brings the same criticisms characterizing the “efficiency defence” within the application of Article 81. In fact, this defence requires such a high standard of proof that it is almost impossible for an undertaking to effectively use it¹¹⁰.

Finally, as already said, the Guidance does not contain any reference to the “legitimate commercial interest” or “meeting competition” as justifications for otherwise abusive conducts. The reason of this absence is unknown, at least for the author.

One possible reason could be that the Commission intends to promote a more stringent approach with respect to the justifications to be used under Article 82, by almost aligning its regime with the one provided for Article 81 cases. This would imply that, apart from situations falling within the category of “objective necessity defence”, the only possible justification would be through efficiencies, by proving the existence of all the above four cumulative conditions.

The other possible (and, in the author’s opinion, more plausible) reason of this absence is that the Commission has merely avoided to give guidance on a broad defence whose scope and ambit of application is still not clear under the European case law. It follows that the existing case law on Article 82 and “legitimate commercial interest” justification, with all their uncertainties, will still apply. As admitted by the same Commission, the Guidance is “without

¹⁰⁹ The Guidance expressly refer to the Commission Communication of 27 April 2004, on guidelines on the application of Article 81(3) of the Treaty, [2004] O.J. C101/97. For an application of the efficiency defence on Article 82 cases, see Commission Decision of 4 July 2007, *Wanaadoo Espana vs. Telefónica*, [2008] O.J. C83/6

¹¹⁰ See *ex multis* C. AHLBORN, J.A. PADILLA, “From Fairness to Welfare: Implications for the Assessment of Unilateral Conduct under EC Competition Law”, European University Institute, 12th Annual Competition law and Policy Workshop “A Reformed Approach to Article 82 EC”, Florence 2007, p.31.

prejudice to the interpretation of Article 82 by the European Court of Justice or the Court of First Instance”¹¹¹.

¹¹¹ Guidance, *supra* note 10, at 3.

4 The Greek Glaxo Case

The ECJ decision in *Sot. Lelos Kai Sia*¹¹² is the first ruling concerning the relationship between the limitation of parallel trade of drugs by a dominant company and Article 82¹¹³.

Before this decision, this issue was the object of two diverging opinions issued by AG Jacobs¹¹⁴ and Ruiz-Jarabo Colomer¹¹⁵.

This chapter will analyse the factual background of the case (para. 4.1), the above opinions (paras 4.2 and 4.3) and the preliminary ruling delivered by the ECJ (para. 4.4).

4.1 *Factual background*

GSK marketed Imigran, Lamictal and Serevent in Greece through its subsidiary GSK AEVE. For a number of years, the latter had entirely supplied its Greek wholesalers, which had in turn distributed the drugs supplied both in Greece and in other markets, particularly Germany and UK.

Citing a shortage, GSK changed its system of distribution in Greece at the end of October 2000. It stopped meeting its wholesalers' orders from 6 November of that year and supplied the products to hospitals and pharmacies through the company Farmacenter AE.

In February 2001, GSK reinstated normal supplies and resumed supplying Imigran, Lamictal and Serevent to the wholesalers, albeit to a limited extent.

The new GSK's supply policy was challenged by some of its wholesalers before the Greek Competition Authority and the Greek Civil Courts.

¹¹² *Sot. Lelos Kai Sia*, supra note 8.

¹¹³ For an overview of the decisions adopted by the French Competition Council, see F. HERRENSCHMIDT, "The French Competition Council and Parallel Trade in the Pharmaceutical Industry: A Step Ahead of the EU Case Law?", (2008), 31(2) W.Comp, p.235.

¹¹⁴ Opinion of AG Jacobs, supra note 6.

¹¹⁵ Opinion of AG Ruiz-Jarabo Colomer, supra note 7.

The Greek Competition Authority made a request for a preliminary ruling to the ECJ, which, notwithstanding the positive opinion of AG Jacobs¹¹⁶, declined jurisdiction on the grounds that the Greek Competition Authority did not fall within the notion of court or tribunal pursuant to Article 234 EC Treaty¹¹⁷.

A second request for a preliminary ruling was then made by the Greek Court of Appeal of Athens. In this case, the ECJ took a decision on the merits, issuing the ruling that inspired the present paper.

In both requests, the ECJ was asked to answer whether the refusal of an undertaking holding a dominant position to meet *fully* the orders placed to it by its pharmaceutical wholesalers due to its intention to limit their export activity and, thereby, the harm caused to it by parallel trade, constitute a *per se* abuse within the meaning of Article 82 or might somehow be justified.

In case of possible justification, the ECJ was asked to clarify whether, within the assessment of the possible justifications, one could consider some specific factors, such as the high level of regulation characterizing the pharmaceutical sector, the state intervention in the price-setting of drugs, the disputable benefits of parallel trade for end consumers in importing countries or the negative effects of parallel trade on the level of revenues of pharmaceutical companies and thus on their capacity to invest in R&D.

4.2 *The opinion of AG Jacobs*

According to AG Jacobs, in assessing the conduct of a dominant pharmaceutical company limiting parallel trade, one should consider: (i) the pervasive regulation of price and distribution in the pharmaceutical sector; (ii) the likely impact of immoderate parallel trade upon pharmaceutical companies in light of the economics of the sector; (iii) the effects of such trade upon consumers and purchasers of pharmaceutical products.

¹¹⁶ Opinion of AG Jacobs, *supra* note 6, at 17-46.

¹¹⁷ Case C-53/03, *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. GlaxoSmithKline AVEE*, [2005] ECR I-4609.

As to the argument under point (i), AG Jacobs noted that the price of drugs in the exporting countries is not the result of the free play of supply and demand but rather an imposition of such countries acting with the aim to reduce the public expenditures. Therefore, when a pharmaceutical undertaking attempts to block parallel trade, it is not thereby seeking to entrench price differentials of its own making, but rather to avoid the consequences which would follow if the very low prices imposed upon it in some Member States were generalised across the Community. Moreover, AG Jacobs stressed the legal and moral obligations upon the pharmaceutical companies to maintain supply in each Member State. Therefore, the activities of the parallel traders risk destabilising the arrangements which pharmaceutical producers are required to establish in pursuit their public service obligations under national and Community law¹¹⁸.

As to the argument under point (ii), AG Jacobs considered some of the economic factors affecting the commercial policy of pharmaceutical companies, already discussed in this paper in the previous para. 2.3 and 2.4. Given these factors and, in particular, the need for the pharmaceutical companies to recoup the costs incurred for the development of new drugs, AG Jacobs held that a strict prohibition for the pharmaceutical companies to limit parallel trade would have three negative consequences. First, it would represent an incentive for the pharmaceutical companies not to market drugs for which they could reach a dominant position in Member States where prices are fixed at low level or to delay the launch of new drugs in those states. Secondly, it would induce the pharmaceutical companies to use more pressure during the negotiations in low-prices countries in order to raise prices, with the effect of reducing output and consumer welfare in those countries. Thirdly, should such countries manage to resist this pressure, parallel trade would provoke a loss of revenues for pharmaceutical companies and a consequent reduction of their capacity to invest in R&D¹¹⁹.

Finally, and as to the argument under point (iii), AG Jacobs found that parallel trade does not have significant positive effects for end consumers in importing Member States and for the NHS, given that the main part of the price differential is absorbed by the parallel traders¹²⁰.

¹¹⁸ Opinion of AG Jacobs, supra note 6, at 84-87.

¹¹⁹ Ibid, at 89-93.

¹²⁰ Ibid, at 97-98.

In light of all the above factors, AG Jacobs held that a restriction by a dominant undertaking in order to limit parallel trade is capable of justification as a “reasonable” and “proportionate” measure in defence of a “legitimate commercial interest”¹²¹.

The AG expressively recognizes that the conclusions he has reached are “highly specific to the pharmaceutical industry” and not applicable to other sectors¹²².

It is noteworthy to point out that AG Jacobs did not actually apply a proportionality test in terms of “indispensability”. In other words, he did not discuss whether there was an alternative and less restrictive measure available to protect the same interest, nor seems he to consider such a test as necessary.

4.3 The opinion of AG Ruiz-Jarabo Colomer

In its opinion¹²³, AG Ruiz-Jarabo Colomer reached conclusions substantially different from the ones of AG Jacobs¹²⁴.

According to AG Ruiz-Jarabo Colomer, a dominant pharmaceutical company which reduces the number of wholesalers’ orders which it processes to the levels necessary to meet demand in a domestic market, with the intention of preventing parallel imports to other Member States by such wholesalers, commits an abuse of a dominant position¹²⁵.

However, this potentially abusive conduct can be objectively justified on three different grounds: (i) matters related to the “market imperfections” (i.e., state intervention in the price setting and duty to supply); (ii) the legitimate protection of “business interests” (i.e., to avoid the negative effect of parallel trade on the investment in R&D); and (iii) the “efficiency defence”, proving the net positive effect for consumers¹²⁶.

¹²¹ For an article supporting this opinion, see D. MACCANN, “*Syfait v. Glaxosmithkline* Article 82 and Parallel Trade of Pharmaceuticals”, (2005), E.C.L.R., p.383. *Contra* C. KOENIG, C. ENGELMANN, “Parallel Trade Restrictions in the Pharmaceuticals Sector on the test Stand of Article 82 EC - Commentary on the Opinion of Advocate General Jacobs in the Case *Syfait/GlaxoSmithKline*”, (2005), 6 E.C.L.R., p.341.

¹²² Opinion of AG Jacobs, *supra* note 6, at 101-102.

¹²³ Opinion of AG Ruiz-Jarabo Colomer, *supra* note 7.

¹²⁴ The impasse created by this opinion is well represented in P. TREACY, W. JENSEN, “The ECJ Needs to Break the Deadlock, (6 may 2008), *Competition Law Insight*, p.3.

¹²⁵ Opinion of AG Ruiz-Jarabo Colomer, *supra* note 7, at 120.

¹²⁶ *Ibid*, at 121.

Once the grounds for justification have been established, the dominant pharmaceutical company must in any case demonstrate that its conduct met the proportionality test, being the same conduct both *unavoidable* and *appropriate*¹²⁷.

From a legal perspective, the above finding is of particular interest for three main reasons.

First, it explicitly recognizes the “efficiency defence” within the application of Article 82, thus following the approach of the Commission contained in the Guidance and responding to the legal writers who lamented its absence¹²⁸. Second, it clarifies that the three possible justifications are not mutually exclusive and can be used by the pharmaceutical companies in parallel. Third, it reaffirms the necessity of the proportionality test within the assessment of any justification of otherwise abusive conducts, without, however, providing any insight on how this test should be applied in actual practice.

The above being said, it has to be noted that, according to the AG Ruiz-Jarabo Colomer, none of the above grounds were nonetheless satisfied in the case at stake.

AG Ruiz-Jarabo Colomer first dismissed the “market imperfections” justification, stating that “though the pharmaceuticals market does not operate under normal competitive conditions, the price regulation system is not completely free from the influence of the manufacturers, which negotiate prices with the Member States public authorities, enjoy a degree of strength in the market and are able to adapt easily to the vicissitudes of health policy, at least as far as medicines are concerned”¹²⁹. Nor AG Ruiz-Jarabo Colomer accepted the argument related to the duty to supply, given the fact that the “needs of patients in the Member States are not subject to sudden changes, except when there are epidemics or pandemics, and consequently the figures for numbers of patients suffering from each condition are reliable and give the companies a degree of predictability which allows them to adapt to the market”¹³⁰.

AG Ruiz-Jarabo Colomer then dismissed also the justification based on the legitimate protection of “business interests”, by arguing the lack of a causal link between any possible negative impact on R&D investment and parallel trade¹³¹. In this respect, the position of the

¹²⁷ Ibid, at 122

¹²⁸ See *ex multis* P.J. LOEWENTHAL, *supra* note 75, p.465.

¹²⁹ Opinion of AG Ruiz-Jarabo Colomer, *supra* note 7, at 93.

¹³⁰ Ibid, at 96.

¹³¹ Ibid, at 109.

AG was extremely severe, defining this argument as “misleading”, since “it is aimed only at seducing public opinion, which is sensitised to the vital importance of R&D for competitiveness, by shifting the focus from business rivalry to research policy”¹³².

AG Ruiz-Jarabo Colomer finally rejected also the last justification related to efficiencies stating that GSK did not “indicate any positive aspect resulting from its restriction of supplies of medicinal products to the wholesalers, except that its profit margins recover, which is irrelevant [...] for the purpose of justifying it”¹³³, nor was GSK “able to point to anything capable of tipping the balance in its favour”¹³⁴.

4.4 *The ECJ decision*

The decision of the ECJ in *Sot. Lelos Kai Sia*¹³⁵ has finally brought a bit of clarity for pharmaceutical companies, even though some uncertainties remain¹³⁶.

This decision has the unquestionable merit to definitively clarify that the particular features of the pharmaceutical sector do not present any reason to depart from the general rules on antitrust law¹³⁷.

The ECJ based this finding on three assumptions.

First, the control of Member States in the price-setting of pharmaceutical products does not remove the price of such products from the ordinary law of supply and demand, since pharmaceutical companies take part in the negotiations and can exercise a strong influence in the their setting¹³⁸.

Secondly, notwithstanding the obligation upon the pharmaceutical companies to supply the domestic market, in case of shortages, it is not for the dominant pharmaceutical companies

¹³² Ibid, at 113.

¹³³ Ibid, at 118.

¹³⁴ Ibid, at 119.

¹³⁵ *Sot. Lelos Kai Sia*, supra note 8.

¹³⁶ P. TURNER-KERR, “Finally a Bit of Clarity for Pharmaceutical Companies; but uncertainties remain: Judgement of the ECJ in *Sot. Lélos Kai Sia EE v. GlaxoSmithKline A EVE*”, (2009), 2 E.C.L.R., p.57.

¹³⁷ *Sot. Lelos Kai Sia*, supra note 8, at 66.

¹³⁸ Ibid, at 61-63.

but for the concerned Member States to intervene, by taking appropriate and proportionate steps that are consistent with national legislation as well as the obligation arising from Article 81 of the Directive 2001/83¹³⁹.

Thirdly, the ECJ clarified that the circumstance that parallel trade of drugs has only minimal benefits for consumers in the importing countries cannot be used by the dominant pharmaceutical companies to justify their *prima facie* abusive conducts. The ECJ found that “parallel trade is liable to exert pressure on prices and, consequently, to create financial benefits not only for the social health insurance funds, but equally for the patients concerned, for whom the proportion of the price of medicines for which they are responsible will be lower” and that “parallel trade in medicines from one Member State to another is likely to increase the choice available to entities in the latter Member State which obtain supplies of medicines by means of a public procurement procedure, in which the parallel importers can offer medicines at lower prices”¹⁴⁰.

The above being said, the ECJ then held that the specific features of the pharmaceutical sector cannot however been ignored when assessing the consistency with Article 82 of conducts aimed at limiting parallel trade.

In particular, one cannot ignore the fact (i) that state intervention in the price-setting of drugs is *one of the factors* liable to create opportunities for parallel trade¹⁴¹ and (ii) that parallel exporters are not subject to the same obligations regarding distribution and warehousing as the pharmaceutical and are therefore liable to disrupt the planning of production and distribution of drugs¹⁴².

In light of the above, the ECJ, making reference to its previous case law in *United Brands*¹⁴³, held that a dominant pharmaceutical company can take *reasonable* and *proportionate* steps to protect its own commercial interests. This means that a dominant pharmaceutical company may therefore refuse to honour orders of its *existing* customers that are *out of the ordinary*.

¹³⁹ Ibid, at 75.

¹⁴⁰ Ibid, at 56-57.

¹⁴¹ Ibid, at 67.

¹⁴² Ibid, at 74.

¹⁴³ *United Brands*, supra note 81.

The ECJ then provides some criteria in order to determine whether an order can be considered as *ordinary*.

In the above assessment, one must take into consideration: (i) the previous business relations between the pharmaceutical company holding a dominant position and the wholesaler concerned and (ii) the size of the order in relation to the requirements of the market in the Member State concerned¹⁴⁴.

These two factors are interrelated in the sense that there must be some connection between the wholesaler's orders and the needs of the domestic market. However, the ECJ made it clear that a distributor may not be prevented from exporting some of its products¹⁴⁵.

To sum up, if an existing distributor places an order for quantities that are out of proportion related to the previous business relations *and* the requirements of the domestic market, a dominant pharmaceutical company can refuse the excess but not reject the order in full.

Conversely, any refusal of *ordinary* orders by existing wholesalers cannot be considered as a *proportionate* and *reasonable* measure to protect a legitimate commercial interest and must be considered in violation of Article 82.

It is easy to imagine that now the fight between wholesalers and pharmaceutical companies will be played before the national courts and competition authorities which will be asked to interpret what *ordinary order* in actual practice means.

Thus far, the Greek Court of Appeal of Athens, which made the request for a preliminary ruling to the ECJ, has not yet taken a decision on the merits.

¹⁴⁴ *Sot. Lelos Kai Sia*, supra note 8, at 73.

¹⁴⁵ D. W HULL, "Limiting Parallel Trade - The ECJ Takes a Second Bite at the Apple in the GSK Greece Case", (25 November 2008), *Competition Law Insight*, p.8.

5 What role for the risk to innovation and efficiencies as justifications

In *Sot. Lelos Kai Sia*¹⁴⁶, the ECJ clearly recognizes the possibility for a dominant pharmaceutical company to restrict the supply of drugs in order to protect its legitimate commercial interests. Two commercial interests were taken into account by the ECJ.

First, the interest of the dominant pharmaceutical company in avoiding reductions of profits because of parallel trade¹⁴⁷. As correctly noted by some authors¹⁴⁸, the ECJ reclassified the R&D issue as an impact of parallel trade on profits. It follows that the threat that parallel trade causes to pharmaceutical companies is given by *a reduction of profits*, without being necessary to assess the impact on their capacity and incentive to invest in R&D.

Second, the interest of a dominant pharmaceutical company not to violate its obligation to entirely and constantly meet the domestic demand¹⁴⁹.

However, at least two other possible justifications can be used by a dominant pharmaceutical company to justify a refusal to supply with the aim of limiting parallel trade: (i) the risk to innovation as “legitimate commercial interest” and (ii) the efficiency defence¹⁵⁰.

As seen in previous para. 3, these two justifications have their own requirements to be met and they involve a different standard of proof for the claimant.

Therefore, before going into the above details (para. 5.2), this chapter will first verify whether there is still room for arguing and claiming the above justifications for a dominant pharmaceutical company after the ECJ decision in question.

¹⁴⁶ *Sot. Lelos Kai Sia*, supra note 8.

¹⁴⁷ Ibid, at 70-71.

¹⁴⁸ C. DESOGUS, F. MÜLLER-LANGER, “Supply Management Strategies and Antitrust Issues in the European Pharmaceutical Market”, February 8, 2009, available at <http://www.emle.org/myupload/desogus.pdf> (last access on 26 April 2009).

¹⁴⁹ *Sot. Lelos Kai Sia*, supra note 8, at 74-76.

¹⁵⁰ See Opinion of AG Ruiz-Jarabo Colomer, supra note 7, at 79.

5.1 Criticisms to the ECJ decision in *Sot. Lelos Kai Sia*

At para. 57 of the decision, the ECJ held that it was not necessary “for the Court to rule on the question of whether it is for an undertaking in a dominant position to assess whether its conduct vis-à-vis a trading party constitutes abuse *in the light of the degree* to which that party’s activities offer advantages to the final consumers”¹⁵¹.

Moreover, at para. 70, the ECJ stated that it was not necessary “for the Court to examine the argument raised by GSK that it is necessary for pharmaceutical companies to limit parallel exports in order to avoid the risk of a *reduction in their investments* in R&D of drugs”¹⁵².

By stating this, the ECJ has not rejected the justifications based on efficiencies and risk to innovation, but simply avoided to take any position on them, leaving these issues opened.

Some commentators argue that risk to innovation and efficiencies, though in principle very welcomed as tools to analyse the justification of *prima facie* abusive unilateral behaviours, should not apply in the pharmaceutical sector. In fact, given the specific features of the pharmaceutical sector, this analysis would be too *unpredictable* to be effectively carried out¹⁵³.

With all the respect, it would seem that these concerns about the feasibility of this analysis have somehow influenced the ECJ.

It has been said that the ECJ, by enabling the dominant pharmaceutical companies only to refuse the *out of ordinary* orders, intended to reach a kind of trade off. On the one hand, parallel distributors can keep on exporting drugs, albeit in a limited extent, thereby generating savings in the importing countries. On the other hand, the dominant pharmaceutical companies do not suffer uncontrolled reductions of their profits and, potentially, of their capacity and incentive to invest in R&D. The ECJ would have therefore found a good compromise between static efficiency and dynamic efficiency¹⁵⁴.

¹⁵¹ *Sot. Lelos Kai Sia*, supra note 8, at 57 (emphasis provided).

¹⁵² Ibid, at. 70 (emphasis provided).

¹⁵³ See previous para. 2.4.4.2. See also C. DESOGUS, supra note 56, p.665.

¹⁵⁴ C. DESOGUS, F. MÜLLER-LANGER, supra note 148, p.33.

Is this really true? Has the ECJ finally found a rule to assess the effect of parallel trade of drugs on consumer welfare, both in the short and in the long run? If so, is the proposed rule suitable to punish only those conducts which actually negatively affect consumer welfare? Unfortunately, the above questions do not seem to receive affirmative answers.

First, it should not be taken for granted that the solution proposed will enable the parallel distributors to keep on exporting drugs, thereby generating savings in the importing countries. The nature of the distribution chain suggests that obtaining market shares needs a minimum scale of operations: parallel exporters must supply a significant number of drugs to local retailers and on a sustainable basis¹⁵⁵. Supply-quota policies could prevent parallel distributors from reaching the above optimal scale of operation, thereby limiting the penetration of parallel trade and the occurring of direct savings for patients and NHS. At the same time, the positive effect that can arise from parallel trade can differ from case to case, according, for example, to the regulatory systems in force in the importing countries. One Member State may have adopted measures to favour parallel trade and transfer the savings to the patients or the NHS not in force in other Member States.

Second, if, as it would appear, the genuine (but left hidden) reason why the ECJ recognized the dominant pharmaceutical companies the possibility to refuse *out of ordinary* orders is to indirectly protect their capacity and incentive to invest in R&D, the solution chosen does not seem convincing.

As seen in previous para. 2.4.4, the economic literature agrees on the fact that the impact of parallel trade on R&D may vary from case to case depending on various factors. To put it simple, the same level of parallel trade may have a different impact on the R&D spend of two different pharmaceutical companies, since, for instance, the shape of their innovation production functions over the R&D cost levels are different.

In all the cases, the criteria suggested by the ECJ to interpret the *out of ordinary* rule, which are based in the previous relationships and the domestic demand, cannot measure and differentiate the above effects. These criteria are surely easier to apply but not suitable for carrying out an analysis of an unilateral behaviour based on its effects.

¹⁵⁵ P. KANOVOS, J. COSTA-FONT, *supra* note 56, p.766.

In light of the above, the solution adopted does not seem in line with the new effects-based approach promoted within the application of Article 82, which, once chosen (in the case of the Commission) and/or accepted (in the case of the European Courts), should always apply, irrespective of the sector in which the unilateral conduct takes place.

On the contrary, the other two justifications based on the risk to innovation and efficiencies appear consistent with the proposed new approach for Article 82, since they require an analysis case-by-case grounded on the effects of the conduct in question.

In addition to the above, it has to be noted that the justifications based on risk to innovation and efficiencies may have a scope of application broader than the rule proposed in *Sot. Lelos Kai Sia*¹⁵⁶, which is not suitable to be applied to other possible *prima facie* abusive conducts, such as a refusal to supply towards new costumers or price discrimination according to the Member State where the drugs will be sold¹⁵⁷. Thus, the adoption of the above two justifications instead of the one proposed by the ECJ should enable the NCAs and national courts to apply the same rules for different kinds of *prima facie* abusive conducts, thereby increasing legal certainty.

5.2 *How to apply the justifications*

Risk to innovation and efficiencies can be put forward by the dominant pharmaceutical companies using two different legal arguments, the one not excluding the other.

First, a dominant pharmaceutical company could justify its conduct aimed at limiting parallel trade stating that such conduct constitute a *reasonable* and *proportionate* measure to protect its capacity and incentive to invest in R&D of new drugs.

In parallel to the above justification, a dominant pharmaceutical company can also put forward *efficiencies*, by demonstrating that no net harm for consumers arises. In this case, the company has the burden to prove all the four conditions contained in para. 29 of the Guidance.

¹⁵⁶ *Sot. Lelos Kai Sia*, supra note 8.

¹⁵⁷ In particular, the out of ordinary rule based on the previous relationships and the domestic requirement is inapplicable in case of new costumers and meaningless in case of price discrimination.

It is clear that the second kind of justification is much more demanding and that the pharmaceutical company will have more chances to succeed with the first one.

5.2.1 Risk to innovation as legitimate commercial interest

As seen in the previous chapter. 3, the notion of objective justification is far from clear in the European case law and the Guidance has made the situation even worse.

However, from a review of the European case law, one can infer the following: (i) notwithstanding the Guidance does not contain any reference to the justification based on the protection of legitimate commercial interests, the latter is still applicable because expressly recognized by the European Courts; (ii) the interest to protect the incentive and capacity to invest in R&D can in principle fall within the notion of “legitimate commercial interest”; and (iii) this justification, unlike the efficiency defence, does not require a balancing test.

However, some uncertainties remain. In particular, a dominant pharmaceutical company willing to put forward this justification may find two main obstacles.

First, it must demonstrate the existence of a link between the parallel trade and the alleged reduction of its capacity and incentive to invest in R&D. This issue has been deeply discussed in the economic literature, sometimes reaching different conclusions. In this respect, particularly interesting is the ruling of the CFI in *GlaxoSmithKline*¹⁵⁸, which, though concerning an Article 81 case and subject to review by the ECJ¹⁵⁹, gives some important insights on the link between parallel trade and reduction of R&D spend.

This case originated by a voluntary notification made by Glaxo Wellcome (now GSK) of its new general sales conditions, in order to obtain a negative clearance or an exemption under Article 81(3). These general conditions provided two different drug prices according to the Member States where the drugs would be sold: the regulated price in case the drugs were sold in the domestic market or a higher price in case the drugs were exported.

¹⁵⁸ *GlaxoSmithKline Services*, supra note 1.

¹⁵⁹ Case C-501/06 P, *GlaxoSmithKline Services v. Commission* (pending case)

The Commission held that these general rules were in violation of Art. 81 and could not be exempted under Article 81(3)¹⁶⁰. On appeal, the CFI partially annulled the Commission Decision in so far it rejected GSK's request for an exemption.

An in depth analysis of this ruling goes beyond the scope of this paper. It suffices to point out that the CFI found that the factual arguments and the supporting evidence submitted by GSK to demonstrate the link between parallel trade and reduction of its capacity and incentive to innovate appeared "relevant, reliable and credible, having regard to their content [...], which is corroborated on a number of significant aspects by documents originating with the Commission"¹⁶¹.

By stating this, the CFI did not say that the argument was well founded nor provided a definitive picture of the Commission's position on that complex question. More simply, given the reliability and credibility of the arguments provided by GSK, the same arguments could be rejected by the Commission only through an in depth examination and serious counter economic arguments and not, as the Commission did, with the lapidary conclusion that it was not proved the causal link¹⁶².

In addition to the above, the CFI also clarified that there is no need for the link between parallel trade and R&D to be *direct*, as argued by the Commission, since Article 81 does not contain such a distinction. It is worth emphasising this finding since it clearly runs counter the Commission's practice contained in the Guidelines on the application of Article 81(3), where it is said that "the causal link between the agreement and the claimed efficiencies must normally also be direct" and that the "link between profitability and R&D is generally not sufficiently direct to be taken into account in the context of Article 81(3)"¹⁶³.

The other obstacle that a dominant pharmaceutical company must face is the respect of the proportionality test. As already seen, how this test should be applied in practice is not clear.

While pursuant to the European case law a measure is justified if proportionate to the threat it is aimed to avoid, the Commission requires an indispensability test to be satisfied so that a

¹⁶⁰ Commission Decision of 8 May 2001, *Glaxo Wellcome*, [2001] O.J. L302/1.

¹⁶¹ *GlaxoSmithKline Services*, supra note 1, at 263.

¹⁶² *Ibid*, at 265.

¹⁶³ Guidelines on the application of Article 81(3) of the Treaty, supra note 109, at 54.

measure is justified only when there are not alternative and less restrictive measures available to reach the same goal.

It is clear from the above that, according to the different notions of proportionality, the standard of proof for the dominant company may significantly vary.

Irrespective of the notion of proportionality chosen, it is advisable for the dominant pharmaceutical company to substantiate as much as possible the negative impact of parallel trade on its capacity and incentive to innovate. While it is true that an obligation to deal may reduce the incentives to innovate, the magnitude of this risk varies from case to case, depending on different circumstances¹⁶⁴. Therefore, the larger the negative impact on R&D proved, the easier will be for the pharmaceutical company to demonstrate the proportionality of its *prima facie* abusive conduct.

5.2.2 Efficiency defence

As to the efficiency defence, while its acceptance in the Guidance is surely a step forward toward a more effects-based approach, the conditions to be met are very strict and difficult (or almost impossible) to prove. In addition to what requested within the application of the objective justification, a company must prove the (i) efficiency gains arising from its conduct, (ii) the indispensability of its conduct (there must be no less anti-competitive alternatives to the conduct that are capable of producing the same efficiencies; (iii) that no net harm for consumers occurs (balancing test); and (iv) that the conduct does not eliminate effective competition.

Apart from the clear existence of an indispensability test, which can be instead questioned within the application of the “legitimate commercial interest” justification, the trickiest conditions are the ones regarding the proof of the efficiency gains and the balancing test.

The main efficiency gain is that limiting parallel trade would lead to a gain in efficiency for interbrand competition in so far it enables capacity and incentive to innovate to be increased. This proposition is based on the very R&D-driven nature of the pharmaceutical sector. Since

¹⁶⁴ See previous para. 2.4.4.

all the companies compete on innovation, a pharmaceutical company would act as a rational economic operator by transferring all the additional profits arising from the limitation of parallel trade into R&D investment. This argument was used by GSK during the notification procedure described in previous para. 5.2.1. Also in this case, the CFI found that the Commission did not properly assess the argument put forward by GSK, lacking any serious prospective analysis in which the Commission should have analysed whether, in the particular circumstances of the case and in the light of the evidence submitted to it, it seemed more likely that the efficiency gains described by GSK would be achieved or not¹⁶⁵.

A dominant pharmaceutical company may put forward also other efficiency gains arising from unilateral behaviours limiting parallel trade and benefiting exporting countries, such as more stability in the supply chain (see previous para. 2.5.3) or the absence of any incentive to delay the launch or entry of new drugs (see previous para. 2.5.4).

However, it has to be pointed out that the difficulty with these efficiency gains does not arise from the demonstration of their existence but rather from their quantification, which is necessary in order to successfully carry out a balancing test.

In fact, while the negative effects of a unilateral conduct aimed at limiting parallel trade are concentrated in the short term and quite easy to calculate, all the efficiency gains of the same conduct will occur in the very long term (with the sole exception of the one related to the supply chain), thus making their quantification more and more complex.

In addition, the natural bias of competition authority will be to privilege the short run benefits instead of the long run ones¹⁶⁶.

The risk is that the efficiency defence, though provided in principle, remain unfeasible in practice.

This was already forecasted by several commentators¹⁶⁷ who, in order to avoid it, suggested the introduction in EU of an approach similar to the one adopted in the USA, where,

¹⁶⁵ *GlaxoSmithKline Services*, supra note 158, at 301.

¹⁶⁶ D. GERARDIN, "Limiting the Scope of Article 82 of the EC Treaty: what can the EU learn from the US Supreme Court's Judgment in *Trinko*, in the wake of *Microsoft*, *IMS*, and *Deutsche Telekom*?", (2004), 41 CMLRev, 1542-1543.

¹⁶⁷ See *ex multis* C. Ahlborn, J.A. Padilla, supra note 110, p.31.

according to the case law in *U.S. v. Microsoft*¹⁶⁸, if a monopolist asserts a efficiency justification that stands un rebutted, then the plaintiff must demonstrate that the anticompetitive harm of the conduct outweighs the efficiency benefit.

¹⁶⁸ *U.S. v. Microsoft Co*, 253 F.3d 34, 346 US App. D.C. 330, at 95-97.

6 Conclusion

With its decision in *Sot. Lelos Kai Sia*¹⁶⁹, the ECJ seems to have pleased all the interested parties. On the day of its publication, the associations of both the pharmaceutical companies and the parallel distributors welcomed the ruling as a personal victory¹⁷⁰.

The decision has also been emphasised by some commentators as “a feasible way to render operational a rule of reason” and as “a good compromise between static efficiency and dynamic efficiency”¹⁷¹.

The rule proposed by the ECJ has the clear advantage that it can be easily applied since it is based on objective criteria, such as the previous relationships between the dominant company and its wholesalers and the requirement of the domestic demand.

Is this a convincing solution then? There are reasons for not believing so.

In an application of Article 82 governed by an effects-based approach, what really matters is the final outcome of unilateral behaviours on consumer welfare. Any unilateral conduct should be therefore assessed in light of its effects, using economic analysis and taking into consideration the specific facts of each single case.

As seen, the rule proposed by the ECJ is unsuitable for such analysis in so far as it cannot actually differentiate amongst those conducts negatively affecting consumer welfare and those increasing it.

In this paper, it has been argued that, given all the specificities of the pharmaceutical sector that make an analysis of the risk to innovation and efficiencies particularly difficult, the ECJ was probably still not ready to embark on such a complex exercise.

¹⁶⁹ *Sot. Lelos Kai Sia*, supra note 8.

¹⁷⁰ C. PRIETO, A. L. SIBONY, A. WACHSMANN, “Un arrêt de la Cour de justice en matière d’importations parallèles dans le secteur pharmaceutique satisfaisait l’ensemble des acteurs”, (2008), 4 *Concurrences*, p.84.

¹⁷¹ C. DESOGUS, F. MÜLLER-LANGER, supra note 148, pp. 32-33.

However, in the near future, the ECJ will be asked to take a position in the pending case regarding *GlaxoSmithKline*¹⁷², where the assessment of the efficiencies arising from the limitation of parallel trade is one of the key points. Even though this case concerns the application of Article 81, the future decision of the ECJ will surely also have an impact into the relationship between limitation of parallel trade and Article 82 and, in particular, on the concrete possibility of using risk to innovation and efficiencies as justifications of *prima facie* abusive conducts.

It is disappointing to note that the Commission, within the Guidance, lost the chance to provide a clear and systematic regime on how to apply objective justifications and efficiencies under Article 82 cases. In particular, there are still too many uncertainties on how to apply the objective justifications, the extent of the proportionality test being the most evident example. This uncertainty creates serious concerns, since a too narrow or too broad notion of “objective justification” may respectively result in an increase of Type I or Type II errors.

With the decentralizing process and the increased emphasis on private enforcement, NCAs and national courts, in order to guarantee a uniform application, should be given guidance on how to apply Article 82.

The hope is that, in providing this guidance, the Commission and the European Courts will be focused on the final objective of any antitrust law: enhancing consumer welfare.

¹⁷² Case C-501/06 P, *GlaxoSmithKline Services v. Commission* (pending case).

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