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Antitrust issues in the European pharmaceutical market: an economic analysis of recent cases on parallel trade‡

Abstract

The European pharmaceutical market is currently experiencing a transition phase where the policy of harmonisation is pursued through the trade liberalisation deriving from a regional exhaustion regime of IPRs, while keeping regulation at a national level, especially for prices and reimbursement mechanisms. These differences in regulation generate price differentials and the consequent possibility to arbitrage, or to parallel trade. While parallel trade traditionally enjoys a significant protection from European Institutions, in the belief that it fosters competition and encourages trade, pharmaceutical companies claim that this form of competition undermines their incentive to innovate and threatens the competitiveness of the European pharmaceutical sector. The paper analyses from an antitrust point of view the impact of companies' pricing strategies, like *dual pricing*, aimed at preventing parallel trade. In particular, the role that the specificity of the pharmaceutical sector, i.e. drug price regulation, has in the anticompetitiveness assessment of *dual pricing* is investigated. From a static efficiency point of view, the crucial issue faced relates to whether price controls impede that parallel trade exert effective pressure on prices of reimbursed products, thereby benefiting consumers. From the dynamic efficiency point of view, the link between parallel trade and pharmaceutical companies' incentive to innovation is examined.

JEL classification: K23, L43, L51, O34
Keywords: price discrimination, parallel trade, pharmaceuticals, price controls.

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‡ *This study was supported by an unrestricted grant from The Merck Company Foundation to the Research Center on Health and Economics (CRES) at Pompeu Fabra University, Barcelona, Spain, center that I visited for three months in 2008.*

Introduction

Despite considerable efforts undertaken by the European Commission over the years[1], the European pharmaceutical market is still characterised by an appreciable degree of fragmentation and heterogeneity among Members States, especially with regards to pharmaceuticals' prices, health care systems and reimbursement mechanisms. Although the European Commission has set up some centralized regulatory functions[2], it has not established a supranational regulatory agency, so that the pricing of drugs and other related decisions are under exclusive competence of Member States.

National price controls mechanisms generate the observable price gaps existing for the same drug in different Member States, although price discrimination strategies applied by pharmaceutical companies also play an important role in this respect.

These price differentials generate the possibility to arbitrage, or to parallel trade. Parallel trade consists in the importation of legitimately produced goods into a country without the authorization of the trademark, copyright, or patent holder.

The legal governing doctrine of parallel trade stems from the European policy on freedom of movement of goods, pursuant to Articles 28-30 of the EC Treaty, and the principle of '*regional exhaustion*'[3]. On this basis, once a good is legally produced and placed onto the market within the European Economic Area by the owner of the right, the latter cannot use its trademark or patent right to hinder the further sale of the

[1] The pharmaceutical sector is one of the most regulated at a Community level (the first Directive dates back to 1965, with the Dir. 65/65/EC), and one of the few subject to a system of transparency of prices (see Directive 89/105/EC).

[2] The Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laid down Community procedures for the authorization and supervision of medicinal products for human and veterinary use, and established the European Medicines Agency.

[3] Unless otherwise stated by the law, the economic exploitation of intellectual property rights is limited to the act of first sale (*first sale doctrine*), when the '*exhaustion of intellectual property rights*' occurs. From that moment the product can freely circulate along the distribution chain within a given market and in those countries where the manufacturer did not apply for the intellectual property right. The fact that intellectual property rights are territorial rights, nevertheless, creates different scenarios once the IPR is exhausted. Indeed, if the principle of '*international exhaustion*' is applied, the IPR is considered exhausted everywhere in the world and re-importation in the country of origin is allowed. Whereas, if '*national exhaustion*' is applied, the IPR is considered exhausted only within the country of origin. It follows that re-importation from other countries is illegal. The '*regional exhaustion*' option is a choice that stands in the middle of the two, whereby free circulation of goods after the first sale is allowed only within the European Economic Area. See for discussion AMMANN, *Intellectual Property Rights and Parallel Imports*, in *Legal Issues of Economic Integration*, 1999, vol. 26, no. 1-2, pp. 91-122; YUSUF and MONCAYO VON HASE, *Intellectual Property Rights and International Trade – Exhaustion of Rights Revisited,* in *World Competition,* 1992/93, Vol. 6, no. 1, pp. 115-131.

product elsewhere in the EEA, except in exceptional circumstances where, for example, public health is at risk[4].

With regards to patents, the European Court of Justice (hereinafter the '*ECJ*') held that "*the exercise, by a patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market*"[5].

Parallel trade of pharmaceuticals started in the '70s but it increased significantly with the maturing of the internal market. From the half of the '90s the share of parallel trade grew up to 7-17%, especially in countries like Denmark, Sweden, United Kingdom, Germany and the Netherlands[6].

The UK market has the highest level of penetration among the four countries mentioned. In the years 2000–2002, the UK market for parallel imports was one of the largest in Europe and was worth around $1, 700 million, that is, about 15% market share and 14% of the National Health Service expenditure[7]. In 2003 parallel imports were estimated to account for 17% of the pharmacy market sales. After a period of stagnation in 2004, the business is now expanding again[8].

Likewise, the German market for parallel trade experienced a rapid growth. Over the period 1998-2003 the market shares of total pharmacy market sales increased from less than 2% to around 7%. In 2002, parallel imports penetration increased significantly, as legislation required pharmacists to source at least 5% of the sales from parallel

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[4] See the jurisprudence on the so-called '*specific subject matter*', initiated with the landmark case C-78/70 *Deutsche Grammophon GmbH v. Metro-SB-Groomarkte GmbH &Co. KG.*, followed by ECJ, 3 July 1974, C-192/73, *Van Zuylen frères v. Hag AG (Hag I)*, and confirmed by ECJ, 31 October 1974, in case C-16/74, *Centrafarm BV et Adriaan de Peijper v Winthrop BV* and ECJ, 31 October 1974, in case C-15/74, *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.* With regards to patents, the Court affirmed that the specific subject matter is the "*guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties, as well as the right to oppose infringements*".

[5] See *Centrafarm v Sterling*, cit., summary, par. 15. This general principle, based on the distinction between the existence and the exercise of patent rights, has been enshrined in EC legislation on industrial property. See article 7 of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trademarks, which reiterates the case law of the ECJ.

[6] The following data are sourced from IMS Health, EFPIA (European Federation of Pharmaceutical Industries Associations), and EAEPC (European Association of Euro-Pharmaceutical Companies).

[7] Data are even more significant in specific cases: Merck & Co estimated that parallel imports for Timoptic (an anti-glaucoma) reached at that time 56% and for Renitec (a cardiovascular drug) 50% of the UK market sales.

[8] See IMS Health, Management Forum, February 2006.

imported products. In 2003 such percentage was set to 7%. In 2004 the reversion of the mandatory quota to 5% reduced parallel import market share correspondingly. However, thanks to favourable market conditions such share increased again to around 8,5% at the end of 2006. The average market share for the 20 drugs with largest turnover is around one third.

In the Netherlands, parallel imports reached about 13% of the market in 2006.

In Denmark, the first approval for parallel import of a drug was given in 1990 and since then marketing authorisation has been granted for 6-8, 000 products. Over the period 1998-2004 the share of total drug expenditures spent on parallel imported products has remained more or less constant at slightly above 12% of total sales of prescription and non-prescription drugs in the primary health care sector. The expenditures on parallel imported medicine in the hospital sector amounts to 2% of total expenditures on drugs in the hospital sector.

The first parallel imported drug was available on the Swedish market in 1997. The parallel distribution sector increased rapidly also in Sweden. The market share of 1,9% in 1997 increased to 6,1% in 1998. By 2000 the market share was 8,6% and reached 12,1% in 2006.

Recent data show that in the period between June 2005 and June 2007 the turnover in all import markets increased by 11,8%, reaching the level of 4600 million Euros. At present, parallel imports represent roughly the 9,1% of the sales in import markets and the 3,2% of the total pharmaceutical sales of the EU 27[9].

Pharmaceutical companies strongly try to prevent the growth of such business. Being forced to compete in importing markets with their own products sold by parallel traders at a lower price, they claim that this form of competition is capable of eroding their profits and undermining their incentive to innovate[10]. Therefore, in order to safeguard their revenue, manufacturers implement different strategies based either on pricing or on supply management.

On the contrary, European Institutions have traditionally given a certain degree of protection to parallel trade, in the belief that it fosters *intrabrand* competition and

9 See IMS Health MIDAS at MAT/JUN/07. Germany, UK, Netherlands, Sweden, Norway, Finland, Denmark, Belgium, Austria are the considered countries. Values are at standard purchase price in importing market. Transaction can be pharmacy sell-in or sell-out.

10 Industry estimates suggest that lost sales in the EU currently amount to some $3 billion per year**.** See *The Wall Street Journal*, 11 April 2002.

promotes integration through intrastate trade[11]. For this reason, the ECJ and the European Commission have over time repeatedly condemned Member States' measures and corporate conducts that, without any appropriate justification, restrict exports[12].

However, after having pursued for almost forty years a policy aimed at protecting and encouraging parallel trade, through the firm prohibition of corporate conducts that restrict exports, Community Courts, following companies' allegations, have recently questioned the legal principles underpinning such a policy with specific regard to their application to the pharmaceutical sector.

In particular, pharmaceutical companies claimed that the specific regulatory and legal and economic context of the pharmaceutical industry impedes the generation of significant consumer benefits from parallel trade in the short term. In addition, it has been argued that parallel trade is also detrimental for consumers in the long term, because it undermines companies' incentive to innovate and to invest in R&D.

Drawing on these recent jurisprudential developments, this paper intends to critically review the economics and the empirical evidence supporting the judicial reasoning.

The discussion is organised as follows:

- Section 1 summarises the most recent jurisprudential trends on parallel trade on pharmaceuticals, as compared to traditional case law.
- Section 2 analyses parallel trade on pharmaceuticals as a form of *intrabrand* competition existing during pharmaceutical patent validity.
- Section 3 investigates the nature of national drug price regulations and the

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[11] See ECJ, ch. V, 16 January 1992 in case C-373/90 *Criminal Proceeding against X*, where the Court said that "*parallel imports enjoy a certain protection in Community law because they encourage trade and help reinforce competition*".

[12] Ex multis see *Deutsche Grammophon v. Metro*, cit.; ECJ, 13 July 1966, in joint cases C-56/64 e C-58/64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*; *Hag I*, cit.; ECJ, 23 May 1978, in case C-102/77, *Hoffmann-La Roche et Co. AG v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse MBH*; ECJ, 1 February 1978, in case C-19/77 *Miller International Schallplatten GmbH v Commission of the European Communities*; ECJ, 12 July 1979, in cases C-32/78, C-36/78 e C-82/78 *BMW Belgium v Commission of the European Communities*; ECJ, 8 November 1983, in joint cases C-96-102/82, C-104/82, C-105/82, 108/82 e C-110/82 *NV IAZ International Belgium and others v Commission of the European Communities*; ECJ, VI ch., 11 January 1990, in case C-277/87, *Sandoz prodotti farmaceutici SpA v Commission of the European Communities;* ECJ, 5 December 1996, in case C-267/95, *Merck & Co. Inc. and Others v Primecrown Ltd. and Others*; and ECJ, 11 July 1996, in cases *Bristol-Myers Squibb v Paranova A/S* (C-427/93) and *C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S* (C-429/93) and *Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S* (C-436/93); CFI, II ch., 21 October 2003, in case T-368/00, *General Motors Nederland BV and Opel Nederland BV v Commission of the European Communities*; and ECJ, ch. III, 6 April 2006, in case C-551/03 *General Motors* BV v *Commission of the European Communities*.

influence that this has on competition.

- Section 4 assesses the existence of savings from parallel trade and how large they are.
- Section 5 specifically considers the role that parallel trade has on price negotiations between governmental agencies and manufacturers.
- Section 6 analyses the link between parallel trade and pharmaceutical companies' incentive to invest in R&D.
- Section 7 concludes.

1. Parallel trade on pharmaceuticals: past and present legal trends

The mentioned jurisprudential *revirement* on parallel trade cases, which stems from the economic-oriented approach advocated within the ongoing process of so-called 'modernization of EC competition law'[13], started with the well-known judgment delivered in the *Adalat* case[14].

In that occasion, the European Court of Justice (hereinafter the 'ECJ') has indirectly ruled in favour of quantity restrictions imposed by Bayer on Spanish and French pharmaceutical distributors. In fact, the ECJ qualified these restrictions as unilateral conduct rather than an export ban falling within the scope of Article 81 EC and, in so doing, it reversed the EC Commission's decision on this specific issue and dissented from previous jurisprudence[15].

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[13] Many commentators considered the application of Article 82 EC from the Commission and the Courts to be too formalistic, following the heritage of the ordoliberal theory, and little in line with economic theory. See GYSELEN, *Rebates: Competition on the merits or exclusionary practices?*, in EHLERMANN *and* ATANASIU, *The European Competition Law Annual 2003: What is an Abuse of a Dominant Position?,* 2003, p. 287; FOX, *Abuse of Dominance and monopolization: how to protect competition without protecting competitors,* in EHLERMANN *and* ATANASIU, *The European Competition Law Annual 2003,* cit., p. 69; FOX, *We protect competition, you protect competitors,* in *World Competition*, 2003, p. 149; AHLBORN and PADILLA, *From Fairness to Welfare: Implications for the Assessment of Unilateral Conduct under EC Competition Law,* presented at EUI for the *Twelfth Annual EU Competition Law and Policy Workshop. A Reformed Approach to Article 82 EC,* 2007; and finally see also the *GCLC Research Papers on Article 82 EC*, 2005.

[14] See ECJ, full court, 6 January 2004, in joined cases C-2/01 e C-3/01 *BAI v Bayer and Commission of the European Communities.*

[15] The concept of 'agreement' has been extensively interpreted by the ECJ, which inferred its existence indirectly through the analysis of parties' behaviour, even in absence of written formalities. For instance, the existence of an agreement has been often based on factual circumstances, like the commercial relationship existing between the parties. Accordingly, the ECJ considered the invoices, sent by the manufacturer to wholesalers, bearing the wording 'export prohibited', as *indicia* of the existence of an implicit agreement aimed at impeding parallel trade, to be integrated the in the existing commercial relationship. See *Sandoz*, cit., summary, par. 13; ECJ, 15 July 1970, in case C-41/69 *ACF Chemiefarma NV v Commission of the European Communities*, par. 12.

Similarly, in a reference request made by the *Epitropi Antagonismou* (i.e. the Greek Competition Commission), the '*Syfait I*' case[16], the Advocate General Jacobs argued, in open contrast with prior case law under Article 82 EC[17], that a pharmaceutical company does not necessarily abuse its dominant position if it refuses to supply wholesalers in order to protect its commercial interests (*read:* its incentive to innovate) from parallel trade.

Nevertheless, the issue of whether the refusal to supply aimed at hampering parallel trade on pharmaceuticals is legitimate or not still was not entirely clear from a legal standpoint. Indeed, while significantly departing from the traditional case law, the outcome of the aforementioned cases did not help to identify clear guidance for handling future cases.

Indeed, in the *Adalat* ruling the ECJ focused its reasoning on the issue of 'the concurrence of wills' when discussing the possible existence of an agreement restrictive of competition. Unfortunately, it did not consider the legal status of supply quotas under EC competition law.

The ECJ dismissed *Syfait I* on procedural grounds since the Greek Competition Authority was not deemed to be a 'Tribunal' within the wording of Article 234 of the EC Treaty. Therefore, the merits of the case were only addressed in the mentioned opinion of the Advocate General.

Three years after the dismissal, the ECJ had to deal with identical questions in the *Syfait II* case[18]. The Advocate General Ruiz-Jarabo Colomer in his opinion refused the reading of Article 82 EC as a *per se* prohibition of abusive conducts and accepted the application of a *rule of reason* in the antitrust analysis, in consideration of possible *efficiency gains* deriving from them[19].

However, the AG contradicted AG Jacobs' previous analysis. Considering the same facts, he affirmed that a dominant company's refusal to supply patented medicines to wholesalers with a view to reducing parallel trade constituted an abusive conduct

[16] See ECJ, 31 May 2005, in case C-53/03, *Reference for a preliminary ruling from the Epitropi Antagonismou in Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and Others (Syfait I).*
[17] See *United Brands,* cit.
[18] See joined cases C-468 to 478/06, *Sotiris Lèlos kai Sia E.E and others v. GlaxoSmithKline AEVE Farmakeftikon Proïonton.*
[19] See par. 72 of AG Ruiz-Jarabo Colomer's opinion in the *Syfait II* case.

that could not be objectively justified by legitimate commercial interests or efficiency considerations.

The Grand Chamber of ECJ reached the same conclusion in its decision, but it brushed efficiency considerations aside. At the same time, it left open the possibility that a pharmaceutical manufacturer might be able to justify a refusal to supply where the orders are out of the ordinary, having regard to size of the order and its impact in the market of the first Member State and the previous course of dealing between the pharmaceutical manufacturer and the wholesaler concerned.

With this recent judgment, the ECJ has then returned to a more orthodox approach towards restrictions to parallel trade on pharmaceuticals but there remains a need to determine on a case-by-case basis when orders are 'out of the ordinary', in order to effectively both prevent and punish infringements. Also, albeit the decision clarified several legal important issues regarding parallel trade in this sector, there remains a question about its impact on pharmaceutical innovation.

With regards to Art. 81 EC, the Court of First Instance (hereinafter 'CFI') in the *Glaxo* case on *dual pricing*[20] affirmed - contrary to the assessment made by the European Commission and prior case law - that such pricing strategy violated Art. 81(1) EC. However, the Court considered the dual pricing system as an anticompetitive agreement not in its object but only in its *effect,* only insofar it impeded consumers to enjoy savings brought about by parallel trade.

Secondly, the Court said that, in evaluating the conditions for a possible exemption under Art. 81(3) EC, the European Commission did not properly carry out the necessary economic analysis, required by the specific nature of the pharmaceutical sector. Therefore, the CFI annulled its decision in that part and required a new evaluation from the side of the Commission.

The ruling is currently under appeal by both parties.

[20] This strategy is a two-tier price model where two different prices are applied to the same good depending on its final destination. If the drug is distributed in the domestic market, a lower price is set; vice versa, a higher price is applied if the drug crosses the border. In this way, the price differential between the low-priced country and the high-priced country automatically disappears, together with the economic incentive to trade for the parallel distributors.

2. Parallel trade as a form of *intrabrand* competition

While a pharmaceutical product is in patent, price competition works only to a limited extent. Its efficacy in fact depends on the possibilities of substitution among equivalents.

First of all, substitution does not operate at the level of patients. Patients are in fact price insensitive, as most of their pharmaceutical expenditures do not come out of their pocket but are covered either by the national health care system, either by private insurance. The fact that pharmaceuticals are *merit goods*[21], i.e. goods that every individual should potentially have at his disposal, even if he or she does not get a concrete utility from it, makes so that access to medicines is commonly granted by the State through consumption's financing. The reimbursement system, however, creates a departure from the classical market functioning, as consumers use products that an agent – the government - pays for him/her.

In addition, patients do not have the appropriate information to single out the distinguishing features between possible alternatives. Being affected by asymmetry of information over the characteristics of a given medicinal specialty (which in this respect is a *'post-experience good'*[22]) and unable to choose among different therapies, they have to rely on the expertise of a physician, who chooses the product on their behalf.

From this it follows that substitution through cheaper products depends in the first place on the economic incentives to which the doctor is subject to and not on the

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[21] The governmental intervention in the financing of drug consumption is economically justified by the fact that merit goods are consumed at a suboptimal level if provided through market mechanisms. In fact positive externalities generated from consumption are not internalised from consumers. In other words, consumers, subject to asymmetry of information over the characteristics of the good, consider only individual utility they get from consumption rather than social benefits deriving from it, especially in the long run. To remedy this market failure, the State can choose to encourage a larger production or consumption of these goods through public procurement, regulation, or financial provision. See DELBONO, ZAMAGNI, *Microeconomia*, 1998, p. 794. The authors underline that "*… l'attribuzione di meritorietà ad un bene presuppone che il singolo individuo non sia pienamente in grado di percepire il contenuto di pubblica utilità associato al consumo di particolari beni o servizi se non dopo averne, più o meno a lungo, sperimentato l'utilizzo. Ne consegue che l'autorità pubblica deve garantirne la diffusa accessibilità*".

[22] *Post-experience goods*, also called *credence goods*, are goods whose qualities and impact over the personal utility, consumers are not perfectly able to judge, even after they consume them. *Credence goods* can present a direct relationship between price and demand, when the price is the only proxy for the quality of the product. Consequently, consumers do not buy expensive products to avoid low quality products. Therefore, producers are induced to fix high prices for *credence goods,* given that consumers are not aware of the fact that they are of low quality. See CABRAL, *Introduction to Industrial Organization*, Massachusetts Institute of Technology Press, 2000, page 223. NELSON, *Information and Consumer Behavior*, 78(2) *Journal of Political Economy*, 1970, p. 311-329.

willingness to pay of the patients. For the reasons just explained, they are, in fact, insensitive to drug price and their demand is inelastic[23].

Secondly, substitution among pharmaceutical products is based on the ATC (Anatomical Therapeutic Classification) classification, which groups the pharmaceutical specialties into therapeutical classes[24]. Substitutability among medicinal products is in fact determined by the therapeutical properties of products rather than by the pharmaceutical form (pills, solutions, etc.) or by the concentration of the active substance.

It follows that products belonging to different therapeutical classes cannot be considered substitutes, even though the pharmaceutical form is the same. But also medicinal specialties belonging to the same ATC class, which in principle should contain a set of therapeutical alternatives, are not perfect substitutes, as the replacement of a drug with another one depends on medical culture, gravity of the disease, and physical characteristics of patients.

Thirdly, the regulatory features of the health care system also determine substitution among drugs. Where, for instance, a physician prescribes a branded product or a product in patent by reference to its generic name, absent appropriate regulation that gives the incentive to provide the cheapest product, the pharmacist is bound to supply the branded product. He cannot offer an alternative product even though it may be pharmaceutically equivalent.

Such a product differentiation is enhanced not only by the diversity of pharmaceutical forms, but also by the fact that some drugs have been developed to cure only a particular disease. This makes so that product markets may have a reduced dimensions, while concentration is high. This, especially for highly specific products, is due to the large investments in R&D necessary to develop such products. The huge amount of resources necessary to discover a new molecule and the high level of risk associated with the inventive activity constitute a natural barrier to entry that can perpetuate oligopolistic structures of the markets. The fact that only a small number of companies has the necessary resources to enter a potential market, and the presence of

[23] It is also possible to consider it as a four-tired structure of demand, where the physician prescribes, the pharmacist dispenses, the patient consumes, and the third-party pays.

[24] The ATC classification has been drawn up by EphMRA (European Pharmaceutical Marketing Research Association). The second ATC level corresponds to therapeutical main groups, whereas the third ATC level reflects therapeutical / pharmacological subgroups.

patent protection reduce and delay the possibilities of penetration of the market from new entrants.

This analysis shows that *interbrand* competition can exert a poor pressure on prices during patent validity, thereby consenting to manufacturers to be *price maker* to a certain extent[25]. That is why the stimulus of *intrabrand* competition, provided for by parallel trade during patent validity, appears to be essential in order to balance the ability of firms with market power to charge excessive prices.

Indeed, imported products, although aesthetically different after repackaging, are chemically identical to the branded correspondents. That means that parallel trade can serve an important twofold purpose: it grants access to medicines, by surmounting therapeutical substitution problems, especially for patients who for physical constraints are bound to take a particular drug, while entailing savings at the same time.

From this it follows that any practice aimed at impeding and restraining this form of *intrabrand* competition impedes consumers to enjoy a wider access to medicines and governments to implement their cost containment strategies through lower prices.

Nevertheless, such effect did not look apparent either to the CFI in the *Glaxo* case or to AG Jacobs in the *Syfait* case, which doubted about the existence of an effective pressure from parallel trade on prices of original products, due to regulatory intervention on drug prices.

3. The specificity of the pharmaceutical sector

In the *Glaxo* case, the CFI affirmed that the application of Art. 81(1) EC could not depend solely on the fact that the agreement affected trade between Member States and partitions the common market. On the contrary, it also required checking whether it prevents, restricts or distorts competition on the relevant market, to the detriment of the final consumer. In other words, the judge affirmed that to be considered contrary to Art. 81(1) EC, the agreement should both impede intrastate trade *and* hinder effective competition in the market[26].

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[25] See LUCIONI, *Economia e normativa del farmaco,* 1998. See also the study conducted for the European Commission from Charles River and Associates, *Innovation in the pharmaceutical sector*, 2001, on the competitiveness of the European pharmaceutical sector, where this market is described through the model of monopolistic competition.

[26] See parr. 118-119 of the *Glaxo* ruling.

The anticompetitiveness of vertical agreements should be carefully analysed in light of the specific features that characterise this market. In the case under discussion, such specificity was identified with the fact that prices are regulated differently across Europe.

In the view of the Court it appeared, firstly, that '*prices are finally set by Member States*'; secondly, that '*prices fall outside the play of supply and demand*'; thirdly, that they are '*established at structurally different levels throughout the Community*'[27].

These characteristics induced the Court to affirm, even after a prior general acknowledgment of the positive effect of parallel trade[28], that it is impossible to presume the existence of such benefits in the pharmaceutical market, given that drug price regulation impedes the occurrence of the competitive pressure traditionally associated to parallel trade[29].

For this reason, the CFI, going against prior case law[30], affirmed that such agreement was not contrary to Art. 81(1) EC in its object but only in its *effect*, insofar it impeded consumers to enjoy savings brought about by parallel trade.

Evidence demonstrated that in the specific case some national health systems did take advantage of the lower prices according to their respective health schemes and translated them into lower pharmaceutical expenditures for the State. Therefore, the dual pricing, as long as it impeded such benefits, was considered anticompetitive.

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[27] See parr. 125-134 of the CFI decision in the *Glaxo* case, and especially par. 134 where the Court affirmed that '*That circumstance means that it cannot be presumed that parallel trade has an impact on the prices charged to the final consumers of medicines reimbursed by the national sickness insurance scheme and thus confers on them an appreciable advantage analogous to that which it would confer if those prices were determined by the play of supply and demand*'.

[28] See par. 107 of the *Glaxo* ruling, where the Court acknowledged that parallel trade is the only form of competition capable of exercising effective pressure on prices during the period of validity of a patent.

[29] See parr. 119-147 of the *Glaxo* ruling and in particular par. 147 where the Court said:' … *As the prices of the medicines concerned are to a large extent shielded from the free play of supply and demand owing to the applicable regulations and are set or controlled by the public authorities, it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers…'*. Cfr. the opinion of the AG Roemer in *Consten and Grundig,* cit., ECR, p. 299, on the role of parallel trade on prices: "… *Parallel imports, which the EC Commission has considered necessary, do not determine a reduction of final prices, but have as effect the provision of substandard services for consumers…* ".

[30] See *Consten and Grundig*, cit.; *Miller*, cit., par. 7; ECJ, 29 October 1980, joined cases C-209 to 215 and 218/78, *Heintz van Landewyck SARL and others v Commission of the European Communities*, parr. 150-156; ECJ, joined cases C-96/82 to 102/82, 104/82, 105/82 and 110/82 *IAZ and Others v Commission*, cit., parr. 23 to 25; ECJ, 8 March 1984, joined cases C-29/83 and 30/83 *Compagnie Royale Asturienne des Mines SA and Rheinzink GmbH v Commission of the European Communities*, par. 26; *General Motors*, cit., parr. 66-68 (citing *IAZ,* paragraph 23) and parr. 101-102, and parr. 63, 69, 71-72, 75 of the Opinion of AG Tizzano on the case. See also *Sandoz*, cit., where Sandoz Italia tried to prevent the Italian wholesalers to export its product abroad, through the application of the wording '*export prohibited*' in the invoices. In that occasion the ECJ identified an agreement between the manufacturer and the wholesalers that was contrary to Art. 81 EC in its object. It should be noted that the CFI did not explicitly confront itself with this previous decision.

On the same wake, in the *Syfait I* case the Advocate General Jacobs supported the idea that a departure from traditional anticompetitive assessment of refusal to supply from a dominant company was justified by the specificity of the pharmaceutical sector.

And again, the specific nature of the legal and economic context in which the pharmaceutical industry operates has been identified by the AG with the fact that drug prices are subject to State regulation[31]. Such interference, responding to public health protection and public expenditures containment goals, would impede normal conditions of competition prevailing in the price formation[32]. From this point of view, thus, the pharmaceutical market is different from other industries.

Furthermore, regulatory intervention through drug price regulation, varying across Member States, and coupled with the public service obligation[33], which obliges pharmaceutical companies to maintain adequate supplies in each Member State, would lock in pharmaceutical companies. In other words, being compelled to supply the export markets, where parallel trade originates, companies cannot defend their profits in the importing markets from competition triggered by cross-border price differentials caused by Member States' different regulation.

The presence of this strict regulatory environment, preventing companies from adopting strategies that would defend their commercial interests from competitors' attack, has been thus claimed to justify the anticompetitive behaviour.

Furthermore, the same features that would justify a dominant's company attempt to prevent parallel trade, according to the AG, would also impede that the latter brings benefits to consumers. On the contrary, parallel trade would benefit only traders who pocket most, if not the entirety, of the price differential[34].

3.1 Drug price setting mechanisms

From a legal point of view, it is correct to base the legal assessment of the effects that an agreement has on competition on the economic dynamics of the sector under

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[31] See on the same wake the CFI decision in the *Glaxo* case, cit., parr. 125-134, where the Court affirmed firstly that '*prices are finally set by Member States*'; secondly, that '*prices fall outside the play of supply and demand*'; thirdly, that they are '*established at structurally different levels throughout the Community*'.

[32] However, see *Centrafarm v. Sterling*, cit., summary par. 2: "*It is a matter of no significance that there exist as between the exporting and importing Member States price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product…*". This principle was confirmed in *Merck v Primecrown*, cit., par. 47.

[33] See Article 81 of the Dir. 2001/83/EC, the so-called 'Human Use Directive'.

[34] See parr. 96-99 of the AG Jacobs' opinion on the *Syfait II* case.

investigation. However, previous case law already established that price differentials and heterogeneity of regulation in the pharmaceutical market do not have any relevance in the evaluation of the anticompetitiveness of restrictions to exports[35].

Indeed, the existence of price regulation does not appear to be the right criterion to treat pharmaceuticals differently from other sectors. Many products and services – like books, postal and banking services – are subject to price regulation *and* competition law. In such sector, the fact that prices are regulated in different ways and differ from State to State does not normally constitute a reason to claim a departure from the traditional judgement of anticompetitiveness of an agreement.

From an economic point of view, on the one hand, it is true that drug prices formation heads off from competition, given that public health protection and public expenditures containment goals play an important role in their determination.

On the other hand, it should be recalled also that distortions to competition come in the first place from the market failures that characterise this sector and that require regulatory intervention[36]. Regulation seeks to achieve prices that strike a balance between the need for cost effective availability of medicines and the pharmaceutical companies' right to earn a fair rate of return[37].

In fact, in those countries where prices are negotiated[38], prices are determined by much the same factors as in other markets even in the presence of regulation. That is, they are function of the willingness to supply of the seller and the willingness to pay of

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[35] See *Centrafarm v. Sterling*, cit., summary par. 2: "*It is a matter of no significance that there exist as between the exporting and importing Member States price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product…*" This principle was confirmed in *Merck v Primecrown*, cit., par. 47; see also *Bristol-Myers Squibb*, cit., and *Centrafarm v. Winthrop,* cit. See *General Motors*, cit. where it was affirmed that lacking harmonisation, it is normal that domestic and export sales are subject to different regulations, albeit this does not modify the anticompetitive features of an agreement.

[36] The pharmaceutical market, indeed, it is characterised by several market failures: the moral hazard associated with the described trilateral relationship, supply-side entry barriers, i.e., patents, the process and length of regulatory approval, product differentiation, and brand loyalty. Efforts to correct these market imperfections has generated a substantial portion of the regulatory interventions to contain costs in the market for pharmaceuticals, as it is believed that competition alone would not be sufficient to secure efficient prices. However, in the literature there are concerns over national drug pricing policies, which could limit competition by intervening on prices. See GREEN, *Is price regulation necessary? A Summary of the arguments, Pharmacoeconomics*, 1998, n. 14, p. 137; DANZON, CHAO, *Does regulation drive out competition in the pharmaceutical market?,* in *Journal of Law & Economics,* vol. 43, 2000, p. 311-357.

[37] See CAPRI and LEVAGGI, *Reconciling social and industrial goals: a bargaining model to pricing pharmaceuticals*, Liuc working paper Economia e Impresa 42, 2005

[38] See European Commission submission to the ECJ to appeal the decision of the CFI in the case C-513/06 *GlaxoSmithKline Services Unlimited v. Commission of the European Communities*, par. 48(d), where it is pointed that in 14 out of 25 EU Member States pharmaceutical companies are either completely free to set their final prices or negotiate them with the authorities.

the buyer, the bargaining and market power of the two parties, the (social) value attributed to the product, the number and characteristics of the alternatives already on the market, and the presence of the availability of reference pricing information, of cross-country price comparisons, as well as of parallel imports.

While it is true that health care agency that have the task to bargain for the price of drugs enjoy the buyer power typical of monopsonists, pharmaceutical companies also have a certain amount of influence over the market.

The authoritative power of health care agencies in setting pharmaceutical prices is mitigated by the provisions of the so-called 'Transparency Directive' (Dir. 89/105/EC). Articles 2.1 and 2.2 of this Directive provides that (i) pharmaceutical companies participate in the price setting procedures, (ii) authorities are obliged to justify objectively the rejection of a company's price, and (iii) companies have the right to market the product at their proposed price if they do not receive notification of the authorities' rejection of the price within ninety days from filing[39].

Secondly, pharmaceutical companies enjoy a substantial degree of market power through the exclusive rights arising from their patents. This advantage is further strengthened by the dossier protection[40] and by the mentioned large (sunk) investments in R&D and by marketing efforts, which constitute a competitive advantage over any potential entrant and thus a barrier to entry. This endows them with a strong bargaining position where prices of medicines are negotiated between the company and the health agency, especially when the product is life saving and does not have effective substitutes available in the market[41].

Pharmaceutical companies' market power is not even constrained by the public service obligation, as this provision cannot prevent a dominant company from meeting wholesalers' purchase orders. Article 81 of the Human Use Directive should not be

[39] See par. 89 of AG Ruiz-Jarabo Colomer's opinion on the *Syfait II* case.

[40] The provision establishing data protection for medicinal products for human use restrict the access to the clinical dossier of reference of medicinal specialties from parties other than the patent owner. Article 14(11) of the European Parliament and Council Regulation (EC) No 726/2004 states: "*Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorized in accordance with the provisions of this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies*". The new periods of protection only apply to reference medicinal products for which an application for authorisation has been submitted after 20 November 2005 (Article 89 of Regulation (EC) No 726/2004).

[41] See par. 84 and 90 of AG Ruiz-Jarabo Colomer's opinion on the *Syfait II* case.

interpreted as mandating companies to enter a specific market. Companies have the right to decide not to enter a market at all (especially if they are offered a price that they consider to be too low). However, if they choose to enter, they are obliged by law to grant 'appropriate and continuing' supplies, in compliance with competition law and the EC rules on free movement of goods.

The fact that pharmaceutical companies have room for manoeuvre in relation to drug prices is demonstrated by anecdotal evidence: in the *Glaxo* case, the price of some of GSK's products, which was subject to parallel trade, was after some time renegotiated with the Spanish government at a higher price, thereby reducing the scope for parallel trade[42]; similarly, in Greece the law establishing pharmaceutical prices changed towards a greater flexibility for the manufacturer[43].

3.2 Pharmaceutical regulation on parallel trade

Furthermore, affirming that drug price controls impede that savings deriving from parallel trade are passed on to consumers implies that price negotiation leads to fixed price at each level of the distribution chain. However, in all Members States where price controls mechanisms are applied, prices are only upper caps, which do not impede to have lower price in the market through competition at the retail level[44].

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[42] See the Commission decision in *GlaxoWellcome*, cit., par. 121, where it is affirmed that GSK obtained a rice increase for four out of eight products subject to parallel trade: Serevent®, Imigran® e Lamictal® in May 1997, and Ventolin® in July 1998.

[43] In 1998, Greece introduced, according to article 20 of act no. 2458/1997, a reimbursement positive list and the lowest reference pricing system among the 15 European Union Member States with the purpose of controlling the growth of pharmaceutical expenditure. The principle criterion for the inclusion of a medicinal product in the list was its therapeutic impact, which was evaluated on the basis of the severity of the disease treated, the product's effectiveness/safety ratio, the availability of alternative treatments with or without medicines, and the target population. Furthermore, in order for a product to be included in the positive list, its average cost of daily treatment, which was calculated by the members of the list Ccommittee, should be equal to or lower than the reference for the pharmaco-therapeutic category in which the product was included. The pharmaceutical industry brought an action against Government policies and the Greek council of state judged in January 2005 that the pharmaceutical pricing as unconstitutional. The court expressed the view that a sole country reference, that of the lowest price in Europe, was by itself an inadequate criterion for assessing the cost and price of a locally produced or imported drug. Hence, the pricing system was found to violate the principles of free trade and fair competition introduced initially by the Treaty of Rome, and should be replaced by a more-rigorous analysis based on price calculations based on more countries. New pharmaceutical legislation, no. 3457, was enacted on May 8th 2006, aiming at greater access to medicines, improvements to citizens' quality of life, effective and efficient utilization of health resources, transparency in public management, protecting public health, and maintaining long-term financial viability of the insurance system. A new pricing system was introduced based on the average of the three lowest European prices, of which two are calculated from the former 15 European Member States plus Switzerland and one from the new states that joined the EU after May 2004. Another innovative aspect of the new legislation is the abolition of the positive list and the establishment of a rebate system granting the National Insurance Funds a rebate rate paid by the pharmaceutical companies.

[44] See European Commission submission to the ECJ to appeal the *Glaxo* ruling, cit., par. 48(c). See also ABBOTT, *Price regulation in the pharmaceutical industry: prescription or placebo?,* in *J Health Econ*., n. 14, 1995,

Policies implemented in several Member States aimed at inducing relevant agents, like wholesalers and pharmacists, to seek for cheaper supplies seem to confirm the willingness of the regulator to create favourable conditions for competition. This, on the one hand, should improve access to medicines and, on the other, relieve public finances.

Table 2: Policies used to Promote Use of Parallel Imported Imports in Selected European countries

Policies that promote Use of PI drugs at pharmacy level	Denmark	Germany	Netherlands	Norway	Sweden	UK
Mandatory information on availability of PI	X	X			X	
Mandatory dispensing of PI drugs if price differential is least equal to a fixed range	X	X			X	
Mandatory quota on PI dispensing rate		X				
Financial incentives to dispense Pi drugs			X	X		X
Financial incentives to dispense lower-priced drugs, including PI				X	X	
Lower consumer out-of-pocket expenses (price or co-payment) for PI products	X		X		X	

Source: P. Kanavos, D. Gross and D. Taylor, *Parallel Trading in Medicines: Europe's experiences and its implications for commercial drug importation in the US*, AARP Public Policy Institute, June 2005, as updated by me through with information from EAEPC members in the course of 2007.

In many Member States reference pricing and parallel import prices play a direct role in setting reimbursement prices (Denmark). In other countries, schemes that claw back (part) of the price reduction obtained by pharmacists from parallel import prices seek to translate such lower prices in savings for the NHS (UK).

Direct pass-through arrangements are also implemented. In Denmark, in Netherlands and in Sweden the pharmacist is required to inform the patient of the

who argues that fixing prices, in theory gives companies both an incentive to produce efficiently and the flexibility to price according to its changing market environment if there is potential for competition below the maximum price.

availability of parallel imported drugs and the patient is charged a lower price if he purchases them. The same applies in Germany but patients do not face lower prices for parallel traded drugs.

Further, in the Netherlands, Germany and Sweden pharmacies are provided financial incentives to purchase parallel traded drugs. Also Norwegian pharmacists face such incentives but pharmacists do not have to inform patients of the availability of these alternatives nor do patients face a lower price for purchasing parallel traded products.

In Germany and in Denmark pharmacists are required to sell the parallel imported product if its price is lower of a certain percentage with respect to the original one[45].

4. Savings from parallel trade on pharmaceuticals: do they exist? …

Economic theory suggests that parallel trade would stimulate savings both directly and indirectly. Direct benefits should derive from the lower prices paid by patients that purchased parallel imported products, which in turn entail lower reimbursement costs for health care systems and lower premium for health insurance. The indirect benefits may potentially derive from the competitive pressure put on manufacturers by parallel importers that drives down patented products prices, or decelerates their increase.

The empirical evidence provided for by the European Commission, and subsequently accredited by the Court itself, confirms the theory. Indeed, in the *Glaxo* case it was demonstrated that some of the drugs subject to the new sale conditions were subject to co-payment in some Member States, and where this was in percentage to the price, patients had some benefits from parallel trade, even if the price differential with the original product was small. Moreover, some national health care systems, according to their respective reimbursement schemes, translated these lower prices into savings for the public budget[46]. In a context where national health systems are considered final

[45] In Germany, as of January 2004, the pharmacist is required to dispense the parallel imported product only if its price is more than 15% cheaper than the original (for values less than €100) or if the price exceeds €15 (for values greater than €100). In Demark substitution with parallel imported products is mandatory for 5 DKK (0.7 €) price difference for prices less that 100 DKK (13 €), for 5% price difference for prices between 100 and 400 DKK (13 to 54 €) and for 20 DKK (2.7€) for prices above 400 DKK (54 €).

[46] See the EC Commission decision *GlaxoWellcome* case, cit., par. 48-52.

consumers[47], the mentioned measures show then that parallel trade is in principle capable of bringing about direct benefits.

With regards to dynamic effects of parallel trade on pharmaceutical prices, an illustrative example is given by the following graph:

Figure 1: dynamic gains from *intrabrand* competition

Source: Pharmacy price list (Poland) - T. Dzitko – 3rd Annual CEE Pharmaceutical Challenges Conference, Budapest, June 2006

The red line identifies the development of the manufacturer's price, while the green and the blue line indicate the price policy pursued by two parallel traders. From the graph it is apparent that the entry from the two competitors accelerated the ongoing downwarding price trend.

Some empirical studies attempted to quantify such effects but found contradictory evidence with respect to their magnitude.

A first study quantified the resulting savings between 1997 and 2002 in five main European Member States: Denmark, UK, Germany, Sweden and The Netherlands. With regards to indirect savings, in general it was found that prices for on-patent drugs

[47] See ECJ, 7 February 1984, in case C-238/82, *Duphar BV and Others v The Netherlands State*, where the Court of Justice has, because of the special nature of the trade on pharmaceuticals, considered national health care systems as substitutes to consumers as with regards to the responsibility for the financing of health expenditures.

without competition increased, whereas prices for on-patent drugs that faced competition from parallel trade decreased [48].

A subsequent study, on the contrary, found little competitive effect and a very small price reduction for on-patent drugs subject to parallel import[49].

The last study on this subject provided counterarguments to the findings of the second study. This study calculated and updated the data relative to the direct and indirect savings for fifty products in the four main European countries: Denmark, Germany, United Kingdom and Sweden[50].

Table 3: Direct savings from parallel trade on pharmaceuticals (in ml €)

	York study	**LSE study**	**Pedersen study**
UK	342	6.9	237
Germany	194	17.7	145
Sweden	47	3.8	45.3
Denmark	16	3	14.2
Total	**599**	**31,4**	**441.2**

Source: York study, 2003; LSE study 2004; Pedersen study, 2006.

The mentioned studies also found evidence, albeit in different size, of indirect savings from parallel trade, especially in Sweden and in Germany.

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[48] See WEST, MAHON, *Benefits to Payers and Patients from Parallel Trade*, University of York, 2003, where the authors considered the competitive effect that parallel imports had on domestic prices in the period 1997-2002 and tried to quantify the resulting indirect savings. The study analysed five main countries, Denmark, UK, Germany, Sweden and The Netherlands, and in general found that prices increased for on-patent drugs without competition, whereas prices decreased for on-patent drugs with competition from parallel trade.

[49] See KANAVOS, COSTA-I-FONT, MERKUR, GEMMILL, *The Economic Impact of Pharmaceutical Parallel Trade – A Stakeholder Analysis*, LSE, 2004. The finding is probably due to the very small and little relevant sample used and to the too simple interpretation of the observed co-movement of prices. Indeed, prices co-movement does not necessarily imply the absence of price effect. On the contrary, if there is co-movement, one should expect also price competition - *à la Bertrand* - where each player will undercut its competitor in order to capture the bigger or even the whole market share. In those cases when to prices co-movement does not correspond competition, it is likely that one of the actors has a monopoly power. The monopolist can use other strategies than price competition. It can, for instance, restrict market supplies and exclude any potential competitor. In this way, its products will not be subject to the competition of parallel traders and no price reduction will be observed in the market

[50] See PEDERSEN ET AL., *The Economic Impact of Parallel Import on Pharmaceuticals,* 2006. The study used a larger sample: the Authors analysed the price series for 50 products and took into account the development of prices over time. The general assumption on which the study is based is that the manufacturers in the absence of competition from parallel imports will set their price equal to the maximum reimbursed price. Therefore, any deviation from this maximum in markets with parallel imports competition can be attributed to competitive effects from parallel imports.

Econometric analysis, based on counterfactual hypothesis, has shown that parallel distribution can result in reduced prices for certain domestic equivalents. However, the measurement of such benefits is not straightforward, because their existence, depending on features of the health care system, is not always immediately visible or easily accountable.

In the United Kingdom, for instance, the identification and quantification of the effect of competition is difficult, as the prices actually paid by pharmacists are not transparent. Due to the fact that authorities do not cap prices but pharmacies' profits, competition does not materialise in reduced pharmacy sales prices. Rather, it shows up only through discounts. And these discounts are not measurable or immediately quantifiable.

In addition, another element impedes the immediate computation of indirect savings in UK. Pressure on prices cannot be measured monthly or yearly, but only every five years when the pharmaceutical price regulation scheme (PPRS) is renegotiated[51]. When a general price cut is introduced at the renegotiation of the PPRS, pharmaceutical companies have two options to meet this price cut: either they reduce all their price by the percentage required or they modulate their price by reducing the price for some drugs more substantially. The analysis of the pharmaceutical prices after the last renegotiation of the PPRS shows that companies applied the modulation option and that they lowered the prices of those drugs subject to parallel trade more than the renegotiation required, as the following table shows:

[51] The PPRS is agreed between manufacturers and the UK National Health Service (NHS). The scheme covers all licensed branded medicines sold to the NHS. Pharmaceutical companies set prices for their products freely, but their profits are capped by the PPRS if their total home sales of NHS medicines in the United Kingdom exceed a certain threshold. The PPRS caps profits by setting 'target' returns on capital employed on all sales. These target returns on capital ('ROC') are based on the historical average value of invested capital. There are two levels of ROC. The NHS uses a general ROC of 21% in determining a company's liability to repay excess profits. A lower ROC of 17% will be used to decide price increase application. Companies are allowed to deduct a percentage of their sales revenue from 'gross' profits as a reward for their R & D investments. When a manufacturer's profits exceed the target ROC, one or more of the following measures may be taken: price reduction, restriction or suspension of price increases requested by the manufacturer, and repayment of excessive profits.

Table 4: Correlation between a reduction in parallel trade activities in UK and price reductions at the renegotiation of the PPRS in 2005

Product	PI % 2004	PI % 2005	Price cut
Lipitor	42.5	14.6	5-17%
Zoton	37.5	42.7	0-1%
Zyprexa	48.6	35.5	0-19%
Plavix	46.2	25.8	0%
Zoladex	66.5	49.2	0-31%
Efexor	28.9	30.8	0-2%
Cozaar	43.7	45.4	-10-0%
Seretide	16.9	17.5	7%
Aprovel	80.9	34.8	24-30%
Serevent	28.7	27.4	0-7%
Cardura	32.6	6.7	0-55%
Risperdal	48.4	39.4	8-14%
Lipostat	30.0	13.2	7%
Fosamax	27.5	42.7	0-1%
Aricept	62.2	62.1	7%

Source: IMS Health, Janice Haigh, Management Forum, Cambridge, 20th February 2005

It should be noted that price cuts higher than the mandatory 7% established in the new PPRS scheme correspond to the highest level of penetration of import in the UK market, thereby suggesting a correlation between these reduction and parallel trade.

4.1 ... And how large they are?

In light of the above, it appears correct to affirm that savings from parallel trade on pharmaceuticals do exist. The relevant question at stake then should not pertain the existence of benefits from parallel trade, but rather how large they are, namely how much competitive pressure parallel trade puts on the market.

In other words, the key issue relates to who pockets the price differential and appropriates the potential benefits coming from parallel trade.

Apart from the effect of supply management strategies implemented by manufacturers[52], intuitively one could say that the level and the distribution of savings deriving from parallel trade depend in the first place on the degree of wholesale and retail competition present in the importing market. Distributors can retain excess profits from exploiting price differences if there are barriers to entry to parallel trading, and if buyers of the imported drugs are unaware of their source and of the sellers' margins. This may be the case where parallel imports are a very limited activity. But economic theory suggests that, where parallel trade is significant, the parallel trader's margins and prices would fall.

This view is reinforced by the fact that the parallel importer has to persuade pharmacies and health authorities to accept the imported drug, which by regulation must be clearly labelled and re-packaged as an import. Given this product differentiation, traders need to give potential purchasers a financial incentive to purchase an imported drug.

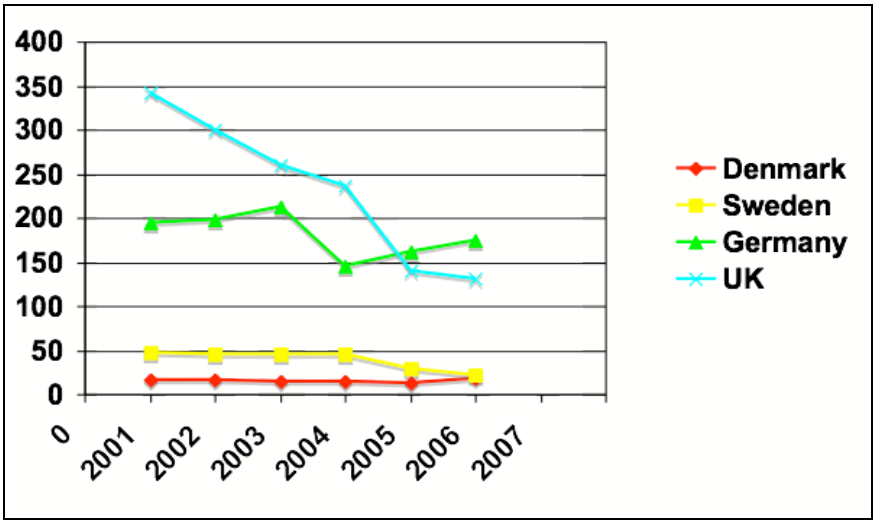
Secondly, regulatory environment certainly influences the magnitude of direct savings.

The magnitude of direct savings appears to have continuously changed over the period 2001-2006 in Denmark, Germany, UK and Sweden[53], as it appears from the table below.

[52] When the manufacturer implements a policy of limitation of volume of parallel trade, i.e. quota systems or supply restrictions, it limits the degree of freedom of parallel trader in setting its profit maximising price or in its ability to undercut the manufacturer. With limited volumes at his disposal parallel distributors are often unable to charge lower prices in the market of destination and lose part of their competitiveness. See at this regard PEDERSEN ET AL., *The Economic Impact of Parallel Import on Pharmaceuticals,* cit., pp. 31. Similarly KYLE, *Strategic Responses to Parallel Trade.* Working paper, in http://www.duke.edu/~mkyle/Research%20Papers.htm, 2005.

[53] The following analysis is based on data sourced from PEDERSEN ET AL., *The economic impact of parallel import of pharmaceuticals,* cit., as well as on information collected through oral interviews of national members of the EAEPC, European Association of Euro-Pharmaceutical Companies. A forthcoming study from PEDERSEN has been commissioned by the EAEPC in order to measure savings in the four countries mentioned for the period 2005-2007.

Table 5: Estimated direct savings from PI in 2001-2006. In Millions €



Source: York study, 2003; Pedersen study 2006.[54]

The explanation for these different trends are mainly to be found in the changes in the regulation that provides different incentives for stakeholders to supply parallel imported products.

For instance, in Denmark savings from parallel trade in 2003-2004 decreased compared to 2001. However, a new increase should be expected as of 2005, given that regulation has been amended in three main aspects that are capable of stimulating parallel imports: the scope for substitution increased, given that the pharmacy is now obliged to offer the cheapest product; that the reference price for reimbursement of drugs changed from the Average European price to the cheapest synonymous Danish product; and that a new formula for the pharmacist price margin incentives cheapest substitution.

Parallel imports accounted for 7% of the total turnover in the German market in the first half of 2003, but only for 4,5-5% of turnover in the first half of 2004. A main reason for the decline is probably the mentioned reduction in the mandatory dispensing of parallel imports from 7% to 5% at the end of 2003. Furthermore, as of 2004 the parallel importers' mandatory discount to sickness funds on the ex-factory price was temporarily increased from 6% to 16%, forcing the withdrawal of one third of parallel

[54] I compare here only two studies out of the three mentioned because of the similarities in the methodology used.

imported products from the German market. However, the reversion of the mandatory rebate to 6% and the new reimbursement system that moved from generic reference pricing to therapeutic reference pricing in 2004 might have inverted the trend in the subsequent years.

The upward trend in the direct savings from parallel trade observed in Sweden between 2001 and 2004 might not have continued in the next years. The pharmaceutical reforms as well and the general price development in the market might have reduced scope for parallel trade. The Pharmaceutical Benefit Act in October 2002 introduced a new reimbursement rule based on cost-effectiveness analysis to determine the reimbursement level of pharmaceuticals, and the mandatory substitution of the lowest-cost generic alternative. Generic substitution was rapidly implemented and the positive attitude to substitution developed by most doctors encouraged generic penetration, which obviously reduces market share of parallel imported drugs.

Secondly, medicine prices have generally decreased by 15% over the period between 2002 and 2005, primarily due to ending of the patent period for a number of top-selling drugs[55], which has opened up for generic products that compete with brand drugs (parallel imports as well as original). The general decline in the market for brand drugs also reduces the potential savings from parallel trade.

The magnitude of indirect savings depends on the total volume of products in the market as well as the degree to which manufacturers respond to increased competitiveness.

While a negotiated price impedes any arbitrary increase in price that does not reflect any change in the demand, the reference price system puts a minimum cap that blocks competition towards the bottom[56]. Often pharmaceutical companies might not want to lower down their domestic prices in response to competition for several reasons. First of all, after a successful price war against a competitor, it is not always possible to raise again prices, as, even in countries where pharmaceutical companies can freely price

[55] E.g.: Zocord®, Losec®, Cipramil®, Plendil®, Zoloft®.

[56] In Italy, for example, it has been observed the absence of any kind of price competition bringing prices below the reference point. See the reports from the Italian Competition Authority No. AS131/1998 *Determinazione del prezzo dei farmaci* and No. AS300/2005 *Disposizioni urgenti per il prezzo dei farmaci non rimborsabili dal SSN*. See also CERM, *Il decreto sui prezzi dei farmaci di fascia 'C' alla luce dell'attività di segnalazione dell'AGCM spunti per 'riflessioni riformiste'*, n. 4/0, 2005. For a general analysis of the influence of regulation on competition see DANZON AND WEI-CHAO, *Does Regulation drive out Competition*, cit.; SANTERRE AND VERNON, *Assessing Consumer Gains from a Drug Price Control Policy in the U.S.*, NBER Working paper series, 2005.

their products, the purchaser could refuse to reimburse the product. Secondly, a lower price for a given product could have a knock-on effect on other European markets, thereby causing a larger loss than the one suffered in the domestic market as a consequence of competition[57].

From this point of view, it is correct to say that health care and pharmaceutical regulation plays a fundamental role in determining the magnitude of the savings and their beneficiaries. Therefore, in recognising that regulation may restrain the occurrence of the competitive process in the formation of pharmaceutical prices, the CFI and the AG Jacobs partially hit the mark.

However, in so doing, they did not consider the economic rationale and mechanisms driving price negotiation, which appears at present the new leading model chosen by governments to control drug prices[58].

5. The role of parallel trade in price negotiations

The bargaining process between the regulator and the company can achieve a twofold outcome: on the one hand, it renders the drug accessible to that part of the population that would have not afforded it on a private market, and on the other hand, it allows the pharmaceutical industry to earn a profit larger than that it would have obtained in the private market. Therefore, the authority, through a successful negotiation, can obtain the enlargement of the target market for the company and the generation of considerable savings for those who had bought the drug anyway[59].

When parallel trade takes place in equilibrium, the allocative function of the bargaining procedure can be enhanced. The threat of parallel trade, in fact, gives bargaining power to authorities and insurance funds *vis-à-vis* companies in price negotiations for domestic products. A larger opening up of the market can be bargained in exchange for a price reduction, to the benefit of public finances on one hand and of firms' profit on the other.

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[57] This was the case of Pfizer in Germany, which, after the inclusion of its product Lipitor in the reference price system and the attribution of the lower reimbursement price of simvastatins cluster, still found to be rational not to lower its price to the reference and to lose most of its market share in Germany, as this would have avoided a larger loss in other markets due the reference price system.

[58] Price negotiation is present at the reimbursement level also in those countries where there is free pricing (e.g. Denmark).

[59] See CAPRI and LEVAGGI, *Reconciling social and industrial goals*, cit.

In presence of parallel trade, price negotiation in the high-price country can take a new dynamic. By the mean of the reimbursement system, the regulator (or the insurance fund) has the power to govern all sales within the country: it could use this power towards the manufacturer, thereby denying reimbursement (or insurance coverage) of the current price and asking for a lower one, under the threat of the alternative source of supply present in the market. The purchasers could for example propose a deal to the manufacturer that leaves a margin of advantage to both of them: by splitting in two the profit earned by the parallel trader, the government could reduce even more its expenditures and the company could recoup part of its lost profits. To this purpose the manufacturer should adjust its price properly.

However, one could imagine an alternative scenario where the purchaser, using the occurrence of parallel trade as a bargaining tool in the reimbursement price negotiations, proposes to the manufacturer to lower down its prices, so that they both gain. Like in a Nash bargaining equilibrium the parties could split equally the profit earned by the trader and agree on a price that makes them both better off[60]. Knowing that price differentials will encourage parallel imports, pharmaceutical companies will seek to establish a domestic price that limits the threat of parallel imports.

This example shows the potential that price negotiation can display in allocative terms when competition takes place. Parallel trade, far from undermining negotiations between governmental agencies and manufacturers, results in the pharmaceutical companies being more favourably disposed to price reductions. Thus price negotiation appears to be the most efficient way to pass on to consumers the savings entailed by parallel trade and to avoid the appropriation from third parties[61].

An anecdotal example at this regard can better clarify such mechanism: Merck Sharp & Dohme (MSD), the UK subsidiary of Merck & Co, in August 2007 voluntarily cut by nearly a third the price of its antihypertensive drug Cozaar, the UK's sixth most prescribed drug. Such a reduction appeared to be strictly linked to the fact that parallel

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[60] See NASH, *The Bargaining Problem, Econometrica,* 1950, no.18, p. 155-162; RUBINSTEIN, *Perfect Equilibrium in a Bargaining Model, Econometrica,* no. 50, 1982, p. 57-109; MUTHOO, *Bargaining Theory with Applications,* 1999.

[61] This general effect has been noted by The Swedish Competition Authority in its review of parallel trade: "*Apart from the direct impact on prices noted above, there are instances of potential parallel imports having an indirect impact on prices. Faced with the prospect of competition from an incipient parallel import trade, some original suppliers of drugs have on occasion voluntarily chosen to cut prices by over 10%, which had the effect of eliminating the conditions necessary for parallel imports.*" See Swedish Competition Authority, *Parallel Imports- Effects of the Silhouette Ruling*, 1999, p. 39.

importers had attained a market share of up to 75% for products of the Cozaar range in the UK, as the following table shows:

Table 6: Price cut operated by MSD on Cozaar in August 2007 matched with parallel import penetration in UK

	UK sales (£000) 3/06 - 3/07	**Old price** (£)	**New price** (£)	**Price reduction**	**PI market share**
Tabs					
25 mg	14.788	18,09	16,18	10,56%	0,00%
50 mg	52.455	18,09	12,80	29,24%	75,09%
100 mg	43.565	24,20	16,18	33,14%	57,27%
Comp tabs					
100/25 mg	1.524	24,20	16,18	33,14%	0,00%
50/12.5 mg	5.912	18,09	12,80	29,24%	60,58%

Source: EAEPC, European Association of Euro-Pharmaceutical Companies

It was estimated that the UK health system would save an approximate £30.2 million per annum due to major price reductions for only one product, provided that that sales volumes of Cozaar products remain constant and on a conservative estimate of a Government claw back rate of 10%. In addition, by retaking 100% of the branded product market in the UK, MSD would gain about £ 30 million per annum in revenues despite reducing its price.

6. *Dual pricing* and the dynamic efficiency gains.

The pharmaceutical industry accounts significant investments in innovation[62], which is one of the main factors determining the competitiveness of a company in the sector. The size of such expenditures requires the companies operating in this sector to recoup R&D costs through a constant and consistent flow of profits, in order to preserve their incentive to invest in research in the long run.

[62] See DIMASI, HANSEN and GRABOWSKI, *The price of innovation: new estimates of drug development costs,* in *Journal of Health Economics,* 2003, n. 22, p. 151, where it is estimated that the cost of developing and bringing to the market a new drug is about eight hundreds millions dollars in year 2000.

On this basis pharmaceutical companies argue that parallel imports, as any other form of price competition, could reduce the resources available for R&D[63]. Therefore, through the elimination of profit losses caused by parallel trade, the company would have availed itself the ability to fully exploit the value of its patent, thus stimulating further research and promoting dynamic efficiency and consumers' welfare[64].

In light of these considerations, in the *Syfait I and Syfait II* cases the defendant contended that the restrictions to exports could be regarded simply as *legitimate business behaviour* finalized to the protection of its commercial interests. In the *Glaxo* case, it was submitted that the dual pricing would have improved the production or distribution of goods and promoted technical and economic progress.

This type of approach raises questions of overriding importance for the application of EC competition law.

From the legal point of view, it could imply that *any* restriction of competition that allows diversion of revenue from 'non innovative stakeholders' (like consumers) to 'innovative firms' is presumed to entail an improvement in innovation and on this basis should escape the application of competition rules[65].

Applied to the *Syfait* cases, such an interpretation would imply that the presence of *ex ante* efficiencies deriving from the unilateral conduct would *always* justify a refusal

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[63] Industry estimates suggest that lost sales in the EU in 2002 amounted to roughly $3 billion per year. See *The Wall Street Journal*, 11 April 2002. In the annual report about facts and figures concerning the European pharmaceutical market, released by EPFIA (the European Federation of Pharmaceutical Industry and Associations), it is affirmed that in 2005 the industry lost 1 million Euros. See www.epfia.org. About the negative effect of parallel trade on profits and on incentive to innovation for pharmaceutical companies see DANZON, *The Economics of Parallel Trade,* in *Pharmacoeconomics,* 1998, vol. 13, n. 3, p. 300; REY and VENIT, *Parallel trade and pharmaceuticals: a policy in search for itself,* in *Eur. L. Rev*., 2004, n. 29, p. 173; KANAVOS, COSTA-I-FONT, MERKUR, GEMMILL, *The Economic Impact of Pharmaceutical Parallel Trade – A Stakeholder Analysis*, LSE, 2004.

[64] However, the theoretical literature is not unambiguous with regards to the effect of parallel trade on manufacturers' profits. Recent literature, in fact, pointed at conditions, like the presence of price regulation, where this can be positive See AHMADI and YANG, *Parallel Imports: Challenges from Unauthorized Distribution Channels*, in *Marketing Science*, 2000, Vol. 19, No. 3, pp. 279-294; RAFF AND SCHMITT, *Why Parallel Trade may raise Producers Profits*, CESIFO Working paper No. 1503, 2005; PECORINO, *Should the US allow prescription drug reimports from Canada?*, University of Alabama Economics Working Paper No. 01-01-04., 2002; GROSSMAN and LAI, *Parallel Imports and Price Controls*, CEPR Discussion Paper No. 5779, 2006; MATTEUCCI and REVERBERI, *Price Regulation and Public Service Obligations under International Arbitrage*, in *Journal of Regulatory Economics*; 2005, vol. 28, no.1, pp. 91–113; SAUER, *A Model of Parallel Imports of Pharmaceuticals with Endogenous Price Controls*, University of Colorado at Boulder Working Paper No. 05-09, 2005.

[65] See JUNOD, *An End to Parallel Imports of Medicines? Comments on the Judgment of the Court of First Instance in* GlaxoWellcome, in *World Competition*, 2007, vol. 30, n. 2, p. 296-298, who affirms that '*…all businesses that are based on innovation rely on money (whether from profits or borrowed funds) to finance innovation. Obviously again, these businesses all wish for more money and more profits in order to finance more innovation. Undeniably, the consumer derives a benefit from the greater number of innovative products that thus come to the market. Nonetheless, this has never been enough to excuse anticompetitive conduct, otherwise one could justify price-fixing cartels, because they too lead to higher profits that can be (and sometimes are) reinvested in R&D*'.

to supply by a dominant undertaking to its rivals. To this purpose, in fact, the defendant should merely observe that its refusal to deal with rivals increases its overall expected profits and that such a profit increase will necessarily bring about the efficiency benefit of increasing the *ex ante* incentive to innovate. This would indicate that a monopolist owner of an intellectual property right would *never* have a duty to supply. However, parallel to the notion that a monopolist does not always have a duty to supply, this principle has been generally rejected[66].

Indeed, although efficiency gains are relevant in the assessment of potentially abusive conducts, they cannot be considered a redeeming virtue *per se*. Therefore, it appears essential that the formulation of both the '*objective justification*' to anticompetitive unilateral conducts and the exemption of agreements restrictive of competition on efficiency considerations is based on sound economics.

In this regard, it could be safely argued that more financial incentives in the form of a broader exclusive right do not necessarily lead to increased innovation. As some commentators have already pointed out, the economic return per invention, which is attributable to patent protection, i.e. the 'patent premium', and the production innovation curve '*are not indefinitely parallel, as at some point, the innovation curve diverges*'.[67] In other words, total appropriation of all possible returns does not necessarily foster more innovation[68].

The effect of parallel trade on R&D depends, for instance, on the shape of the innovation production function over the research and development cost levels. Assuming diminishing returns to scale from investment on innovation, there will be cost levels at which the marginal productivity is high and at which the effect of reduced research and development costs on innovation will be substantial. At the same time, there will also be cost levels at which marginal productivity is low and where this effect is moderate or negligible[69].

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[66] See ELHAUGE, *Defining Better Monopolisation Standards,* cit., par. 306.
[67] See HUMPE and RITTER, *Refusal to Deal*, in *GCLC Research Papers on Article 82 EC*, 2005, p.151.
[68] See LEMLEY, *Property, Intellectual Property and Free Riding*, 83 *Texas Law Review*, 2005, p. 1057, who says that "*Sufficient incentive … is something less than perfect control*"; LESSIG, *Intellectual Property and Code*, *Saint John's Journal of Legal Commentary,* 1996, no. 11, p. 635; BRUNELL, *Appropriability in Antitrust: How much is enough?, Antitrust Law Journal,* 2001, no. 69, p. 1; and further LANDES and POSNER, *An Economic Analysis of Copyright Law*, *Journal of Legal Studies*, 1989, no. 18, p. 325.
[69] See PEDERSEN ET AL., *The Economic Impact of Parallel Import on Pharmaceuticals*, University of Southern Denmark, 2006, p. 16.

Also, it would be excessive to grant blanket immunity to intellectual property rights on the basis that the limited duration and scope of these rights already reflects a trade-off between the exclusion of competition and the promotion of innovation[70]. Indeed, although the scope and duration of an exclusive right is typically the same in each category of intellectual property rights, there are important differences with respect to the value of the underlying investments protected by these rights[71].

In other words, the impact that parallel trade has on dynamic efficiency is not the same in all cases, and certain limitations on a property owner's right to exclude competitors may have only a marginal effect on investment decisions[72]. Thus it appears more appropriate to say that, while parallel trade may curtail incentives to innovate, the magnitude of that risk varies from case to case.

6.1 The proof of the efficiency gains

These considerations shed some light on one of the aspects of the debate over the modernization of Article 82 EC, about whether efficiency considerations are indeed part of the balancing exercise between the short-run effects and the long-run effects deriving from a dominant undertaking's conduct, or whether their mere existence, absent quantification, would be sufficient to escape the application of Article 82 EC.

Under the first approach, the company claiming that its conduct entails efficiency gains has also the burden of proving their concrete existence[73]. It follows that in this way the inquiry under Article 82 EC constitutes the mirror image of the '*bilan economique*' under Article 81(3) EC[74].

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[70] In No. 00-62 *CSU, LLC v. Xerox Corp.*, the DOJ opposed categorical antitrust immunity for refusals to license in its brief to the Supreme Court opposing certiorari. See Brief for the United States as Amicus Curiae at par. 10 (expressing "*serious concerns about such a holding*" and stating that the U.S. "*would not be prepared to endorse it*").

[71] The rewards flowing from the right to exclude can also exceed what is required to induce the necessary investment. Consider that not all new medicines introduced in the market can be considered a breakthrough innovation, as many of them are on the contrary so-called '*me too*' drugs, bearing a much lower social value and a lower investment in R&D.

[72] The importance of the magnitude of such impact is supported by AYRES and KLEMPERER, *Limiting Patentee's Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, in *Mich Law Rev*, no. 97, 1999, p. 987-990, who affirmed that '*unconstrained monopoly pricing is not a cost-justified means of rewarding patentees because the last bit of monopoly pricing produces large amounts of deadweight loss for a relatively small amount of patentee profit. […] Restricting the patentee's monopoly of a small amount is likely to increase social welfare because the benefit of reducing the deadweight loss of supra-competitive pricing is likely to outweigh the cost of a slightly lower incentive to innovate.*'

[73] See parr. 70 and 118 of AG Ruiz-Jarabo Colomer opinion in the *Syfait II* case.

[74] The identification of a two-tier analysis in the context of Article 82 EC can be traced back to Prof. Ulmer who acknowledged the necessary existence of two features in order for a conduct to be considered abusive: the significant impairment of the opportunities of rivals on the market, and the absence of a performance-

Under the second approach, however, the burden of proof rests with the competition authority/plaintiff, which should demonstrate that the conduct complained falls out of the scope of Article 82 EC, for example by proving the loss of possible efficiencies[75]. The company would only have to show that there is evidence of potential efficiency gains and not the full burden of proving that they outweigh the negative effects[76].

However, this interpretation overlooks that fact that in considering the welfare implications of a conduct restricting parallel trade, it is necessary to consider two dimensions: the short-term harm to consumers (or losses in static efficiency) and the long-term benefits to consumers (or gains in dynamic efficiency)[77] [78].

An undertaking's strategy preventing parallel trade always involves some static efficiency loss and some dynamic efficiency gain. Following the so-called "rule of reason" standard, *ex post* static efficiency gains, which can be maximised by an obligation to deal, should be weighed against the *ex ante* dynamic efficiency gains, which could be preserved by not imposing such a duty. On this view, a practice that restricts parallel trade falls within the scope of competition rules where static losses prevail over dynamic gains.

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based competition. See LOEWENTHAL, *The defence of 'Objective Justification' in the Application of Article 82 EC,* cit., p. 458, citing Prof. Ulmer's work. This is also the approach that the *DG Competition Discussion Paper on the application of Article 82 of the Treaty to exclusionary abuses*, cit., where at par. § 84 it states that for the "efficiency defence" to be admitted the dominant company must demonstrate that the following conditions are fulfilled: (i) that efficiencies are realised or likely to be realised as a result of the conduct concerned; (ii) that the conduct concerned is indispensable to realise these efficiencies; (iii) that the efficiencies benefit consumers; (iv) that competition in respect of a substantial part of the products concerned is not eliminated. See criticisms: EVANS and PADILLA, *Designing Antitrust Rules for Assessing Unilateral Practices: A Neo-Chicago Approach*," in *University of Chicago Law Review*, 2005; AHLBORN, DENICOLÒ, GERADIN, and PADILLA, *DG Comp's Discussion Paper on Article 82: Implications of the Proposed Framework and Antitrust Rules for Dynamically Competitive Industries,* 2006; AHLBORN and PADILLA, *From fairness to welfare: implications for the assessment of unilateral conduct under EC Competition Law*, cit.

[75] Notice that it is a consolidate principle of law that *negativa non sunt probanda* and it is, therefore, obvious that the authority cannot bear the burden of proving the *absence* of efficiencies. Similarly see par. 68 of AG Ruiz-Jarabo Colomer on the *Syfait II* case.

[76] The evidential burden of proof is the establishment of a *prima facie* case, i.e. evidence that, if left uncontradicted and unexplained, could be accepted as a proof. For theories supporting such interpretation see NAZZINI, *The wood began to move: an essay on consumer welfare, evidence and burden of proof in Article 82 cases,* cit., p. 51.

[77] By '*static efficiency*' it is meant the allocative effect achieved through the lower prices brought about by parallel trade, while by '*dynamic efficiency*' it is identified with the new and better products discovered thanks to the stimulation of R&D.

[78] On this point see VERNON, *Examining the link between price regulation and pharmaceutical R&D investment,* in *Health Economics,* 2005, n. 14, p. 10; BRUNELL, *Appropriability in Antitrust: How Much is Enough?*, cit., p. 20, who affirmed that '*[a]cknowledging that the long-term welfare effects of dynamic efficiency gains are far more significant than short-term allocative efficiency gains does not mean that any possible diminution in incentives, no matter how remote, ought to trump significant and certain short-term gains*'.

It follows that the analysis of potentially anticompetitive strategies presupposes that the existence and the magnitude of the efficiency gains are actually proved.

According to the efficiency principle, it is up to the party in the best and cheapest position to gather the relevant information that provide the proof. And clearly, while the antitrust agency might suffer from information asymmetry in this regard, the undertaking is better placed to collect and provide evidence.

In the cases under analysis, however, the defendant was not able to empirically demonstrate either the existence of a causal link between parallel trade and the company's reduced incentive to invest in R&D, or the diminished value of its patents caused by parallel trade[79].

With regards to the reduced value of the patent, it is important to note that in the last ten years, there has been a dramatic increase in the cost of pharmaceutical research[80]. The causes are manifold and can be traced to the advent of molecular biology for the basic research, which require the use of expensive technology, the higher complexity of products, the higher hurdles imposed by regulation, etc. This has been noted by the AG Ruiz-Jarabo Colomer in the *Syfait II* case. He, in fact, expressed the view that the reduced profitability of pharmaceutical patents claimed by the manufacturer was caused by the cost structure of the company rather than by parallel trade[81].

With regards to the level of investments in R&D, the defendant's claim is apparently contradicted by evidence showing that R&D expenditure has been growing steadily over the last twenty years, despite the increased penetration of parallel imports in some markets such as the United Kingdom and Denmark[82].

As stated by the AG in *Syfait II*, the company's claim only showed the company's expectation of being in a position to recoup lost profit, without actually demonstrating that such extra-profit would have spurred innovation and promoted efficiency to the benefit of consumers[83].

6.2 The proportionality of the conduct

[79] See par. 109 of AG Ruiz-Jarabo Colomer's opinion on the *Syfait II* case.
[80] The cost of pharmaceutical research, according to the report *Innovation in the pharmaceutical sector - A study undertaken for the European Commission,* delivered by Charles River Associates in 2004, p. 11, had a five-fold increase for clinical trials and of 60% for pre-clinical trials.
[81] See par. 109 of AG Ruiz-Jarabo Colomer's opinion on the *Syfait II* case.
[82] See Parexel's Pharmaceutical R&D Statistical Sourcebook 2003/2004, pp. 1, 289, 296 covering R&D spending within EFPIA countries (EU-15, excluding Luxembourg, plus Switzerland and Norway).
[83] See parr. 116-118 of AG Ruiz-Jarabo Colomer opinion on the *Syfait II* case.

Pharmaceutical companies' allegations about the effect of parallel trade on R&D are grounded on the theoretical assumption that there is a positive correlation between the expected return from drug innovation and the level of investment in R&D[84].

Proving such correlation is very difficult, especially in the pharmaceutical market. The level of overall innovation in the pharmaceutical sector is, in fact, the outcome of the interaction between regulation, the costs of R&D, patent law, the degree of competition faced by companies, the expected profitability of an R&D project, the interest rate, the exchange rate fluctuation, the uncertainty of demand etc.[85] Therefore, patents seem to be merely one of several devices to which firms resort in order to cash-in the monetary returns of an invention, and the patent premium is as important to innovators as other factors of success, such as first-mover advantage, successful marketing, secrecy of the invention, the ability to move quickly down the learning curve, superior service, or network effects[86].

In addition, given the long period that is typically necessary (10-15 years) in order to develop new molecules and to bring them onto the market, as well as the complex regulatory context in which the pharmaceutical industry operates, the reasons that could have led to a lower amount of resources devolved to research can be manifold. For instance, the 'domino effect' of reference pricing systems is capable of reducing profits not only in the European market but also at a global level. Furthermore, the expiry of one or more patents and the subsequent arrival of generics on the market force companies to lower their prices in order to sustain competition, thereby reducing profits.

It follows that parallel trade is not the only determinant of the discovery rate of new drugs. Conversely, parallel trade can only have an *incremental impact* on firms' profits and, on the basis of the magnitude of such incremental impact, potentially also on R&D investments.

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[84] See WIGGINS, *The Pharmaceutical Research and Development Decision Process,* in *Drugs and Health: Issues and Policy Objectives*, 1981, pp. 55-83; GRABOWSKI and VERNON, *The Determinants of Industrial R&D expenditures in the pharmaceutical industry,* in *Drugs and Health,* 1981, vol. 10, pp. 201-215; MYERS, *The Inter-relationship between Pharmaceutical R&D and profit,* in *Journal of Research in Pharmaceutical Economics,* 1992, n. 4, p. 79; SCHERER, *Pricing, Profits, and technological progress in the pharmaceutical industry*, in *Journal of Economic Perspectives,* 1993, n. 7, Vol. 3, p. 97; SCHERER, *The link between gross profitability and pharmaceutical R&D Spending,* in *Health Affairs,* 2001, n. 20, p. 216.

[85] See NERA CONSULTING, *Key Factors in Attracting Internationally Mobile Investments by the Research-Based Pharmaceutical Industry*, A Final Report prepared for UK Trade and Investment and the Association of the British Pharmaceutical Industry, 2007.

[86] See par. 110 of AG Ruiz-Jarabo Colomer's opinion on the *Syfait II* case on a similar point.

The empirical analysis necessary to determine the outcome of the inquiry under Article 82 EC, is complex. The features of the market, the role of regulation and the significant time lag between the possible reason of the erosion of profits and the effect on innovation turn the identification of a robust causality link into a hard task.

This gives raise to sever practical problems. Firstly, Courts do not have the necessary skills to conduct this type of empirical investigation. Secondly, this creates uncertainty in the market, given that the result of an inquiry could vary to a great extent depending on the outcome of the empirical assessment[87].

For these reasons, while it appears correct from the theoretical point of view that dynamic efficiency considerations enter the antitrust analysis of anticompetitive practices, nevertheless the uncertainty inherent in the *rule of reason* constitutes an obstacle to its practical application.

In light of these considerations, Courts should narrow down their approach to the issue. The relevant question should be whether a more lax legal approach to restrictions on parallel trade would achieve the goal of stimulating innovation and foster competitiveness to the European pharmaceutical sector.

For instance, such an approach would trigger the question whether the refusal to supply by company was proportionate to the proposed goal, or whether there are other means to achieve it.

EC case-law suggests that an 'objective justification' can immunize the conduct from the application of Article 82 EC provided that it complies with the principle of proportionality, i.e. the conduct has to pursue a legitimate aim, be reasonable and proportionate to the threat posed by its competitors[88] [89].

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[87] See ELHAUGE, *Defining Better Monopolisation Standards,* cit., p. 307; FLETCHER, '*The Reform of Article 82: Recommendations on Key Policy Objectives",* Speech at the Competition Law Forum in Brussels, where he affirmed that the balancing exercise goes beyond the skills of antitrust agencies and creates uncertainty from the firms' side. See also PITOFSKY, *Policy objectives of competition law and enforcement,* in EHLERMANN and ATANASIU, *The European Competition Law Annual 2003,* cit., p. 127, who said that there are limits to what enforcement officials, judges can deal with in terms of economic complexity; MELAMED, *Exclusionary Conduct Under the Antitrust Laws: Balancing, Sacrifice, and Refusals to Deal,* in *Berkeley Technology Law Journal,* 2005, no. 20, p. 1249; O'DONOGHUE, *Verbalizing a General Test for Exclusionary Conduct under Article 82 EC*, cit., p. 15, who affirmed that '*A firm embarking on a course of unilateral conduct ex ante may be unsure as to where the balance between pro-competitive and anticompetitive aspects lies and when such effects will materialize. Much would depend on the effect of a practice on the dominant firm's rivals, which the dominant firm cannot generally be expected to know. Moreover, what a firm expects* ex ante *may of course turn out to be different from what occurs* ex post'.

[88] See *United Brands,* parr. 189-190, where the ECJ affirmed that the application of the proportionality principle to Article 82 EC presupposes that the conduct of the dominant company is suitable and necessary and not excessive means to the protection of its commercial interests. See CRAIG and DE BÚRCA, *EU Law,*

In particular the European Commission and the Courts have clearly affirmed that a dominant company does not have the right to an automatic and immediate retaliation against a customer that becomes a competitor and that any response should be proportionate.

For example, in *BBI v. Boosey & Hawkes (Interim Measures)*, the Commission held that the mere establishment of a close commercial relationship between a distributor and a competitor of the dominant company does not normally entitle the latter to withdraw all supplies immediately or take any reprisal against that customer[90].

In *United Brands,* the ECJ also made clear that, although a dominant undertaking is entitled to take reasonable measures to protect its commercial interests when these are attacked, such action must be proportionate and cannot respond to the purpose of strengthening its dominant position[91].

In this respect, it appears that AG Jacobs did not consider whether a less drastic, and therefore more proportionate, action from GSK could have achieved the goal of spurring pharmaceutical innovation. On the contrary, AG Ruiz-Jarabo Colomer observed that European law provides different policy instruments aimed at spurring innovation and revitalize the European pharmaceutical sector such as the tax credit, the block exemption for technology transfer agreements and of R&D agreements[92].

From this, it rightly follows that GSK's conduct was disproportionate to the threat posed by parallel trade and inappropriate if its object was to protect the competitiveness of the company[93].

2003, p. 1030; and TRIDIMAS, *Proportionality in Community Law: Searching for the Appropriate Standard of Scrutiny,* in ELLIS, *The Principle of Proportionality in the Laws of Europe,* 1999, pp. 65-84.

[89] In this context, the following four-stage analysis has been suggested: (1) there should be an efficiency or another legitimate objective other than exclusion of competitors; (2) the conduct should be 'suitable', i.e. capable of achieving the legitimate goal; (3) the conduct should be 'necessary', in the sense that there is no alternative that is equally effective in achieving the legitimate goal; (4) the conduct should be "proportionate", in the sense that the legitimate objective pursued by the firm should not be outweighed by the exclusionary effect. See DOLMANS, *Efficiency Defenses Under Article 82 EC Seeking Profits Or Proportionality? The EC 2004 Microsoft case in context of Trinko*, 24th Annual Antitrust and Trade Regulation Seminar, NERA, Santa Fe, New Mexico July 8, 2004.

[90] See Commission Decision 1987/500/EEC – in *BBI/Boosey & Hawkes* IV/32.279: interim measures, par. 19.

[91] However, it should be noted that differently from *Commercial Solvents* in this case there was no leveraging, i.e. no purpose of expanding the dominant position to another market. See at this regard ROUSSEVA, *The Concept of 'Objective Justification' of an Abuse of Dominant Position: can it help to Modernise the Analysis under Article 82 EC?*, in *Competition Law Review,* Vol. 2, no. 2, 2006, p. 46.

[92] See the Reg. EC of the 29 November 2000 n. 2659, applying Article 81.3 EC to agreements on R&D. In particular see Recital 10 of the Regulation.

[93] See parr. 113-114 of AG Ruiz-Jarabo Colomer's opinion on the *Syfait II* case.

7. Conclusions

In recent cases dealing with pharmaceutical companies' strategies aimed at impeding parallel trade on pharmaceuticals, the jurisprudence seemed to have abandoned the approach to the provision as a *per se* or quasi *per se* prohibition in favour of the application of a *rule of reason.*

The main thesis, which generated such approach to the cases, proceeds as follows: in the presence of price controls, parallel trade could not be presumed to bring about any effective pressure on prices of original products and consequently benefits for consumers.

This paper showed that price regulation cannot be presumed to impede price competition in importing markets and that benefits from parallel trade do exist, as confirmed by the fact that health care systems in the importing countries generally take appropriate measures in order for public finances to benefit from the presence of cheaper products in the market.

The investigation conducted tried to face the issue at stake by re-formulating it. It is believed, in fact, that the relevant question related to parallel trade on pharmaceuticals is not whether it entails savings for consumers but rather how large they are. Country-specific regulation and market dynamics could, in fact, impede the full exploitation of the potentials that parallel trade displays and fail to entirely pass savings on to consumers, thereby allowing traders or other stakeholders along the distribution chain to pocket them.

However, the recent diffusion of negotiation procedures as a method to determine drug prices seems to be an efficient indirect pass-through mechanism. When parallel trade takes place in equilibrium, the latter plays like a threat that increase the bargaining power of authorities and insurance funds *vis-à-vis* the companies in price negotiations for domestic products. It follows that, by helping regulators to convince manufacturers to charge lower prices, parallel trade can serve the purpose of achieving allocative efficiency goals.

From the dynamic point of view, it has been analysed whether recouping financial resources through to the elimination of competition provided by parallel trade would serve the purpose of stimulating innovation, to the benefit of consumers, and

would therefore constitute a valid 'objective justification' for the refusal to supply or an exemption to the application of Article 81(3) EC.

Given the heavy role of regulation, and the length and the uncertainty that characterise the discovery process in the pharmaceutical market, it appears very difficult to single out such a correlation. In addition, an exemption granted on the basis of such reasoning would be based on the critical assumption that more money brings more innovation.

Such an assumption does not appear to be empirically verified. In the analysed cases there was insufficient evidence that the defendant's conduct has led to *efficiency gains*, given the absence of empirical support necessary to justify such conduct as against the negative effects cause on competition.

The consideration of efficiency gains in the antitrust analysis of potentially anticompetitive unilateral conducts is clearly very important. Nevertheless, when applied to the pharmaceutical sector, the inquiry involves an analysis of future outcomes that leads to a scrutiny under Article 82 EC based on an unpredictable empirical investigation.

The uncertainty brought by the *rule of reason* can severely increase the administrative costs of the use of the rule, which gives rise to doubts about its practical application by the Courts. In such circumstances, it would be perhaps be preferable that the policy objective of spurring pharmaceutical innovation is achieved through other instruments available under European law, where outcomes are more certain.

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EPFIA, European Federation of Pharmaceutical Industries and Associations
EAEPC, European Association of Euro-Pharmaceutical companies