Abstract

The European pharmaceutical market is currently in 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 a static and dynamic welfare point of view the impact of pricing strategies, like dual pricing, adopted by companies to prevent arbitrage. In particular, the effect of such strategies is analysed in the light of the three goals identified in the literature as the objectives to be achieved by an optimal pharmaceutical regulation: equitable access to medicines, cost containment and improved efficiency.

Keywords: price discrimination, parallel trade, pharmaceuticals, price controls.
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 procedures\(^2\), it has not established a supranational regulatory agency, so that the pricing of drugs and other related decisions are under exclusive competence of each Member State.

Different 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’. On this basis, once a good is legally produced and placed on the market within the European Economic Area by the owner of the rights, the latter cannot use its trademark or patent right to hinder the further sale of the product elsewhere in the EEA, except in exceptional circumstances where, for example, public health is at risk\(^3\).

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

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\(^1\) 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).


\(^3\) Ex multis see cases C-56 e 58/64 Consten v. Grundig, C-78/70 Grammophon GmbH v. Metro-SB-Gromarkte GmbH &Co. KG, C-15/74, Centrafarm v. Winthrop C-16/74, Hoffmann La Roche v. Centrafarm C-102/77, Centrafarm v Sterling C-267/95 e C-268/95, Merck v Primecrown e C-71/94, C-71/94 e C-73/94 Bristol-Myers Squibb and Others v. Paranova.
the rules of the EEC Treaty concerning the free movement of goods within the Common Market."4.

Parallel trade increased significantly with the maturing of the Internal Market and from the half of the ‘90s the share of parallel imports grew up to 7-17%, especially in countries like Denmark, Sweden, United Kingdom, Germany and the Netherlands5. Recent data show that the business, after a period of stagnation in 2003-2004 particularly in the UK6, is continuing to expand, thanks to the greater variety of products involved7.

Pharmaceutical companies strongly try to prevent the growth of such business, because they claim that this constitutes a form of competition capable of eroding their profits and undermining their incentive to innovate8. Indeed, in the importing markets manufacturers compete with their own products being sold by parallel traders at a lower price. In their view, parallel trade entails losses that divert money from R&D purposes. Therefore, to safeguard their revenue and their incentive to invest in research, manufacturers implement different strategies, based either on pricing or on supply management.

On the contrary, parallel trade has generally governments’ and public policy’s support9. I will argue that such a favourable attitude at a national level originates from

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4 See ECJ, 31 October 1974, in case C-15/74, Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc., summary, par. 15. The cited judgment belongs to the jurisprudence on the so-called ‘specific subject matter’, initiated with the landmark case Deutsche Grammophon, cit. With regards to patents, 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". 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.

5 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. The German market for PT has experienced a rapid growth, mostly over 2002, as legislation required pharmacists to source at least 5.5% of the drugs from outside markets. In the Netherlands, parallel imports have reached about 13% of the market, while in Denmark they account for around 10% of the total drugs bill. Data are even more significant in specific cases: Merck & Co estimates that parallel imports for Timoptic (an anti-glaucoma) reaches 56% and for Renitec (a cardiovascular drug) 50% of the UK market sales. See IMS Health, EFPIA-European Federation of Pharmaceutical Industries Associations, the Health Economics Consortium of York University, and EAEPC-European Association of Euro-Pharmaceutical Companies.

6 See IMS Health.


8 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.

9 As practical examples of governmental support to parallel trade we can consider the intervention of the Swedish government in the ‘Syfait case’ (ECJ, 31 May 2005, Grand Chamber, C-53/03, Synetairismos Farmakopoiion Aitolias & Akarnanias (Syfait) and Others v. GlaxoSmithKline plc) in support of the Greek wholesalers who claimed their right to be supplied by GlaxoSmithKline, which contrarily refused or put quotas to supplies of products that were exported to Northern countries, alleging its right to protect its
the savings entailed by parallel trade in the importing countries. In fact, this form of competition could represent a relief for public finances, directly, by providing cheaper prices for drugs, but most of all indirectly, acting as a powerful bargaining tool in the hands of national health systems in the price negotiations.

Similarly at a Community level, European Institutions have traditionally given a certain degree of protection to parallel trade, in the belief that it fosters *intrabrand* competition and promotes integration through intrastate trade\(^{10}\). For this reason, the ECJ and the Commission have over time repeatedly condemned Member States’ measures or corporate conducts that, without any appropriate justification, restrict exports\(^{11}\).

However, in the pharmaceutical sector, a process of re-thinking of the legal principles that drove such policy seems now to emerge.

This trend appears to stem, on the one hand, from the European political agenda initiated with the Lisbon strategy, aimed at recouping the competitiveness of the European economy, especially in innovation-based sectors, like the pharmaceutical one, and on the other hand, from the process of modernization of European competition law towards a more economic oriented approach.

At a jurisprudential level, the turning point in this respect can be identified with the well-known decision on the *Adalat* case, where the ECJ has sentenced in favour of quantity restrictions imposed by Bayer on Spanish and French distributors, thus reversing the Commission decision\(^ {12}\). Similarly, the opinion expressed by the Advocate commercial interests. Another example, which shows the interest of regulators for parallel trade also outside Europe, is given by U.S. Supreme Court decision in *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281 (1988), where it was upheld the Customers service’s policy of not excluding parallel imports of trademarked goods whenever the U.S. trademark holder and the trademark holder in the country where the parallel imports originated are commonly owned or controlled.

\(^{10}\) 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”

\(^{11}\) *Ex mult\(i\)s* see ECJ, 13 July 1966, in joint cases C-56/64 e C-58/64 *Etablissements Costen S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community; Deutsche Grammophon*, cit.; ECJ, 31 October 1974, in case C-16/74, *Centrafarm BV et Adriaan de Peijper v Winthrop BV*; ECJ, 23 May 1978, in case C-102/77, *Hoffmann-La Roche et Co. AG v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse MBH*; 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 Paranov A/S (C-427/93) and C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranov A/S (C-429/93) and Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranov A/S (C-436/93)*. It should be noted that the Court underlined that the existence of price differentials due to different national regulations does not provide any justification to practices restrictive of parallel import.

\(^{12}\) See ECJ, full court, 6 January 2004, in joint cases C-2/01 e C-3/01 *BAI v Bayer and Commission of the European Communities*. It should be noted that such approach has been followed also at a national level. See at the national level the recent decision of the *Conseil de la Concurrence* n. 07-D-22 of the 5 July 2007, where
General in the *Syfait* case, supported the idea that a pharmaceutical company in dominant position can refuse to supply its wholesalers, if its intention is to protect its commercial interests from parallel trade\(^\text{13}\). These arguments seem to appear again in the ruling from the Court of First Instance (hereinafter ‘CFI’) in the *Glaxo* case on dual pricing, where the judge opened the door to a jurisprudential exception to the legal assessment of the anticompetitiveness of pricing agreements aimed at preventing parallel trade in the pharmaceutical sector, on the basis of the specificity of the latter\(^\text{14}\).

Drawing on the *Glaxo* case, this paper intends to investigate the welfare effects of dual pricing, defined as a two-tier price model, where two different prices apply to the same good depending on its final destination.

In Section 1 the facts of the case are presented.

Section 2 analyses dual pricing not only as a device that allows manufacturers to keep on price discriminating in the face of arbitrage, but as a form of price discrimination itself. The analysis shows that such a pricing model implements *de facto* an export ban and studies how cross border trade is affected.

Section 3 examines from a static efficiency point of view the consequences of dual pricing on availability and price of medicines for patients in the importing countries.

Section 4 looks at the crucial issue that determined the outcome of the *Glaxo* case: the existence and the magnitude of savings entailed by parallel trade and how the latter is influenced by regulation in the form of price control mechanisms.

Section 5 considers the benefits entailed by dual pricing from a dynamic efficiency perspective, specifically investigating the existence of a correlation between parallel trade and the slowed rate of innovation claimed to affect the competitiveness of the European pharmaceutical market.

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\(^{13}\) See, *Syfait*, cit., where the ECJ dismissed the preliminary ruling on procedural grounds.

1. The dual pricing system: the Glaxo case

On 6 March 1998, GlaxoSmithKline (formerly GlaxoWellcome; hereinafter ‘GSK’) notified to the Commission a set of general conditions of sale to pharmaceutical wholesalers established in Spain, with the aim of obtaining negative clearance.

The new sale conditions contained a clause that fixed two different prices for sales of the same products to the same customers, depending on the final destination of the product. A higher price applied to purchases intended for resale outside Spain. The lower prices applied only to products intended for subsequent resale at a national level, through pharmacies or hospitals.

GSK required wholesalers to sign immediately the new sale conditions and suspended supplies to those who did not sign. And when it suspected that wholesalers exported products purchased under the new clause, it issued a supplementary invoice.

The new sale conditions were designed in order to stop parallel trade\(^{15}\) and GSK argued that this system generated contribution to technical progress, since more profit could have been devoted to R&D, and distribution could have been improved by stopping diversion of products from low-price countries to high-price countries.

The European Commission, in its Decision of 8 May 2001, found that the new sale conditions constituted an agreement having as its object to prevent, restrict and distort competition; that it actually produced restrictive effects on competition; and that GSK had not demonstrated that the agreement fulfilled the four conditions required from Art. 81(3) EC to obtain an exemption from the application of competition law rules.

Following action brought by GSK before court, seeking the annulment of the decision of the Commission, on 27 September 2006 the CFI delivered its judgement.

The CFI, going against prior case law\(^{16}\), affirmed that agreement was not contrary to Art. 81(1) EC in its object but only in its effect, insofar it impeded consumers

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15 However, at the beginning of the investigation from the Commission, GSK provided a different justification of the implementation of the dual pricing system. See the Commission decision on the GlaxoWellcome case, cit., par. 21. Subsequently GSK admitted that the real objective of the new sale conditions was the elimination of parallel trade. See par. 116 of the decision.

16 See Consten and Grundig cit., p. 341; 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. See also ECJ, 1 February 1978, in case C-19/77 Miller International Schallplatten GmbH v Commission of the European Communities; and ECJ, VI ch., 11 January 1990, in case C-277/87, Sandoz prodotti farmaceutici SpA v Commission of the European Communities, summary, 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.
to enjoy savings brought about by parallel trade. This conclusion was driven by the fact that, being prices of pharmaceuticals regulated by national authorities, parallel trade could not be presumed to bring a real competitive pressure on prices. Therefore, no restriction in the object of the agreement could be proved. Nevertheless, facts demonstrated that in the specific case some national health systems did take advantage of the lower prices according to their respective health schemes and translate them into lower pharmaceutical expenditures for the State. Therefore, the dual pricing, as long as it impeded such benefits, was to be considered anticompetitive.

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

2. **Same drug, different prices: international price discrimination or justified difference?**

The dual pricing scheme is a two-tier price model, where two different prices apply to the same good depending on its ultimate destination. If the drug is distributed in the domestic market, the manufacturer charges a lower price. *Vice versa*, it charges a higher price if the drug crosses the border. From this point of view, it could be thought of dual pricing as a form of geographical price discrimination.17

Economic theory developed different articulated definitions of price discrimination. The most followed in the literature is Stigler’s definition, where there exists price discrimination when two similar goods are sold at two different prices that

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17 It could be also called third degree price discrimination. This notation follows the well-known classification operated by [Pigou, *The Economics of Welfare*, 1920, pp. 240-256, after which it is customary in economics to distinguish among first degree, second degree and third degree price discrimination. First degree price discrimination - a theoretical model that is unlikely to occur in practice because of absence of perfect information - occurs when a firm is able to charge to each consumers his reservation price for each unit of a given good, thereby ripping off completely the consumers’ surplus and eliminating the deadweight loss eventually caused by pre-existing monopoly prices. If, on the one hand, this result can be considered welfare enhancing, however on the other hand, it does not address distributional concerns and social costs resulting from ‘rent seeking’ behaviours. At this regard see [Posner, *The social cost of monopoly and regulation*, J. Polit. Econ., 1975, no. 83, p. 807 - 828. Second degree price discrimination occurs when a firms sets a price per unit that varies according to the quantity purchased by the buyer or when it applies a two part tariff composed by a flat fee plus a variable fee that depends again on the quantity purchased. In this way prices differ across unit of the goods but not across people, so that buyers enjoy some consumers’ surplus. See [Tirole, *The Theory of Industrial Organisations*, 1988, p. 134.](http://example.com) Second degree price discrimination occurs when a firms sets a price per unit that varies according to the quantity purchased by the buyer or when it applies a two part tariff composed by a flat fee plus a variable fee that depends again on the quantity purchased. In this way prices differ across unit of the goods but not across people, so that buyers enjoy some consumers’ surplus. See [Tirole, *The Theory of Industrial Organisations*, 1988, p. 134.](http://example.com) [Stigler, *The Theory of price*, 1957, pp. 209-215.](http://example.com)
are in different ratios to marginal cost. For the same reason, price discrimination in an economic sense occurs also when identical units of a good are sold at the same price under different cost conditions. Vice versa, there is no price discrimination if different prices reflect the difference in the cost of serving different consumers, i.e. it is cost-based. It follows that, strictly economically speaking, there is price discrimination only when price difference is demand-based.

The EC Treaty does not give a definition of price discrimination, but only states that the application of ‘dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage’ is either considered as an abuse, if it comes from one or several firms holding a dominant position, or is prohibited as incompatible with the common market, if it results from an agreement between two or more undertakings.

European competition law in principle does not preclude an undertaking from setting different prices in various Member States. That is, uniform price across Europe is not to be regarded as compulsory. On the contrary, ‘differences in transport costs, taxation, customs duties, the wages of the labour force, the conditions of marketing, the differences in the parity of currencies, the density of competition may eventually culminate in different retail selling price levels according to the Member States’.

The two-tier price model contained in GSK’s new sale conditions could then be justified by the difference in demand elasticity in the domestic market and in the importing country. That is, dual pricing could be considered an application of the

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19 This is also the definition found in the Office of Fair Trade’s Competition Act Guidelines 414.
21 See TIROLE, The Theory of Industrial Organisations, cit., p. 134, who also specifies that it should not be inferred that price discrimination does not occur when differentiated products are sold to different consumers, as the use of different qualities of services is also partly an attempt to capture consumers’ surplus by separating consumers in different groups. See also WHISH, Competition Law, 1993, Third Ed., p. 503, where the difference between price discrimination and price differentiation is underlined, the latter being based on different supplying costs. The Author also pointed out the difficulty in finding an objective justification of different prices on the basis of different costs.
22 The ECJ extended this notion to the case of similar conditions applied to unequal transactions. See ECJ, 17 July 1963, in case 13-63, Italian Republic v. Commission, in the context of the ECSC Treaty.
23 See Art. 82.2(c) of the EC Treaty.
24 See Art. 81.1(d) of the EC Treaty.
25 See Deutsche Grammophon, cit., summary, par. 7, where the ECJ held that “the difference between the controlled price and the price of the product re-imported from another Member State does not necessarily suffice to disclose [an abuse within the meaning of Article 82]; it may however, if unjustified by any objective criteria and if it is particularly marked, be a determining factor in such abuse”; see also United Brands, cit.; Hoffmann-La Roche, cit.; ECJ, 9 November 1983, in case C-322/81, NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities.
26 See United Brands, cit., par. 228.
Ramsey rule\(^\text{27}\), where different prices are charged to different groups of consumers depending on their purchasing power\(^\text{28}\). The higher price applied to exported goods is aligned with a lower price sensitivity of the demand in the importing country, whereas the lower price for domestically distributed goods reflects the higher price sensitivity of Spanish patients.

While allowing the application of dissimilar prices to different retail markets, European case law established that, on the contrary, companies are not allowed to exploit at the distribution level different market conditions at the retail level, by charging different prices to their customers. That is, equation of supply and demand can be taken into account only at the level of the market at which the supplier operates. It follows that manufacturers cannot charge distributors the price “the market can bear”\(^\text{29}\), as it looks unfair to apply different sale conditions to customers belonging to the same class.

To test whether such price differences are justified or not, it looks essential to examine whether commercial transactions are equivalent. In the case under examination, such a comparability test presents interesting but controversial aspects.

To ascertain the equivalence of transactions, one should look in the first place at the characteristics of products involved, which in the specific case are identical in intrinsic quality – chemically and structurally - and in external packaging.

Nonetheless, the equivalence of the transactions must be determined as a whole. Therefore it is also necessary to carry out an overall assessment of the commercial factors characterizing the transactions. For instance, it is necessary to ascertain whether the pharmaceutical wholesalers subject to the new sale conditions implemented by GSK belong to the same category.

Prima facie, transactions appear to be equivalent, since they were performed in the same geographical market, under the same degree of competition and the same regulatory constraints.

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\(^{27}\) This concept was attributed to J. Robinson in 1933, but later on it has been recognized that Ramsey found this result before in the context of taxation (RAMSEY, *A Contribution to the Theory of Taxation*, in *Economic Journal*, 1927, no. 37, p. 47-61). The rule was subsequently applied by Marcel Boiteux (1956) to natural monopolies.

\(^{28}\) Therefore in the case of third degree price discrimination, prices do not differ across units of the good, like for the case of second degree price discrimination, but among individuals or groups of consumers.

\(^{29}\) See *United Brands*, cit., par. 227.
However, the equivalence of transactions is also strictly related to the relevant market where the customers operate\textsuperscript{30}. Among pharmaceutical wholesalers located within a country there are pure domestic wholesalers, pure exporters and wholesalers that engage in both activities. This could induce to envisage a difference in the nature of activity – domestic distribution for wholesalers and cross border trade for exporters - and in the target markets – the domestic one and the importing ones.

As the CFI observed, ‘where it supplied one or other of those national markets, a Spanish wholesaler operated having regard in particular to the relevant regulatory framework, and to the conditions of competition which, as regards to price, the parameter specifically concerned by dual pricing, were heterogeneous’\textsuperscript{31}.

The differences among national regulations on pricing and reimbursement of the medicines, different brand and packing strategies, different distribution systems, as well as different prescribing habits of physicians strongly support the view that those markets constitute distinct relevant markets from the geographical point of view\textsuperscript{32}.

The belonging of the same product to different relevant markets, depending on whether it is domestically distributed or exported, implies that customers, and consequently transactions, are not comparable and therefore price differentials could be justified. In fact, according to case law, different prices can be applied to separate geographic markets that are characterized by insufficiently homogeneous conditions of competition, regard being had in particular to the relevant regulatory framework\textsuperscript{33}.

However, it could also be objected that national health system are not totally isolated one from the other: for instance, national prices do not reflect only the degree of competition and the type of regulation within a country, but through reference price

\textsuperscript{30} See SPRINGER, Borden and United Brands Revisited: A comparison of the elements of Price Discrimination under E.C. and U.S. Antitrust Law, in ECLR, 1997, no. 18, p. 45, who recalls that, if a product could be used for different purposes in accordance with different economic needs, there could be a separate market for each specific use of the product. In his view then, the manufacturer in that case is applying an “inter-market discrimination”, by dividing customers in two different groups according to the use of the products.

\textsuperscript{31} See the Glaxo case, cit., par. 178.

\textsuperscript{32} Such a fragmentation along national borders is confirmed by the fact that, even after the entry into force of a procedure enabling pharmaceutical companies to apply to the European Agency for the Evaluation of Medicinal Products (EMEA) for the purpose of obtaining a single market authorisation for the entire Community, pharmaceutical companies still continue to apply mainly for national market authorisation. See Commission decision in the GlaxoWellcome case, p. 24.

\textsuperscript{33} Tetra Pak v Commission, cit., par. 92 to 96 and 161, 164, 165, 167 and 170.
systems, used both internally and externally\textsuperscript{34}, they also echo market conditions at a European (and even world-wide) level.

Although this might not be the case between Spain and UK, given that the former would not make reference to higher prices than its own ones, and that the latter does not regulate prices at all, still in general terms it could be possible to envisage an economic link among different geographic markets. This enlarged notion of geographical market is supported first of all by the global dimension of R&D costs, which accrue indistinctly and in the same proportion to all countries, and secondly, also by the trade liberalization deriving from the regional exhaustion regime of IPRs.

When taking a pan-European definition of the geographical relevant market, the circumstance that a product object of a certain transaction is either domestically distributed either exported, cannot induce to consider such transactions non equivalent from an economic point of view. It follows that the dual pricing scheme, as it provides for the application of dissimilar conditions to equivalent transactions, falls within the legal category \textit{ex Art. 81(1)(d) EC}.

2.1 \textbf{The effects on cross border trade}

In the context of Art. 81(1)(d) EC\textsuperscript{35}, the application of dissimilar conditions to equivalent transactions has to affect trade between Member States and prevent, restrict or distort competition within the common market, in order to be considered illegitimate.

Geographical price discrimination in itself, in fact, does not constitute a barrier to freedom of movement of goods. Actually, it represents an incentive to intrastate trade. On the contrary, attempts to put obstacles to such a trade can represent a concern, as they run against integration and effective competition in the internal market. Accordingly, impediments to intrastate trade in the context of price discrimination have been commonly considered to be inherently contrary to Art. 81 EC\textsuperscript{36,37}.

\textsuperscript{34} Internal reference price – where the reimbursement price is set accordingly to the lowest among domestic prices of essentially similar products – is applied by Denmark, the Netherlands, Ireland, Norway, Italy, Greece and Portugal; external reference price – where the reimbursement price is set on the basis of the lowest among the price applied in other Member States – is applied in the Netherlands, Germany, Belgium, Italy and Greece.

\textsuperscript{35} In the context of Art. 82, the prohibition of artificial price differences in the various Member States applies as long as it places customers at a disadvantage and distort competition in the context of an artificial partitioning of national markets. See ECJ, 14 November 1996, Fifth Chamber, C-333/94, \textit{Tetra Pak International SA v Commission of the European Communities}, par. 160.

\textsuperscript{36} See ECJ, 5 April 1976, II ch., in case C-27/76 R, \textit{United Brands Company and United Brands Continentaal BV v Commission of the European Communities}, where it was found that \textit{United Brands} charged widely different prices to its distributors in different Member States according to the destination of the bananas, although
The dual pricing system does not limit itself to apply different prices in different Member States. Indeed, the analysis of the prices contained in the GSK’s sale conditions reveals that this pricing strategy is mainly intended to discourage or impede intrastate trade.

In general, prices set forth by the dual pricing clause look over-proportional with respect to prices set outside Spain: almost all prices are higher than the European average, sometimes in percentages that vary roughly from 20% to 30% (see bold green); additionally, some prices (see bold red) appear to be simply aimed at stopping trade between Spain and other European countries, without really showing an alignment with market conditions in the latter38, as the following table shows:

Table 1: Comparison of prices fixed by GSK’s new sale conditions with UK prices and European average price (prices in Euros)

<table>
<thead>
<tr>
<th>Name of products</th>
<th>Spain (domestic sales)</th>
<th>Spain (exports)</th>
<th>UK</th>
<th>EU</th>
<th>Δ% (ES-UK)</th>
<th>Δ% (ES-EU)</th>
<th>Trade ES-UK?</th>
<th>Trade ES-EU?</th>
</tr>
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<tbody>
<tr>
<td>Becotide Inh. 200 x 50 mcg</td>
<td>2,03</td>
<td>13,49</td>
<td>6,03</td>
<td>5,04</td>
<td>119%</td>
<td>167%</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Becloforte Inh. 250 mcg x 180 d.</td>
<td>12,31</td>
<td>21,94</td>
<td>25,65</td>
<td>20,75</td>
<td>-</td>
<td>5,4%</td>
<td>Yes</td>
<td>No</td>
</tr>
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they were sold in the same two ports (Rotterdam and Bremerhaven). The ECJ condemned the discrimination practice applied by the company as contrary to art. 82(c), since it entailed a “partitioning of the national markets” at price level. See also CFI, 6 October 1994, T-83/91, Tetrapack v. Commission (No. 2), upholding Commission decision Elopack v. Tetrapack (No. 2), 92/163/EEC, where geographical price discrimination that compartmentalised the Internal Market was condemned.

37 See the decisions of the EC Commission 78/163/EEC in case IV/28.282 — The Distillers Company Limited – Conditions of sales and price; 82/203/EEC in case IV/30.188 — Moët et Chandon (London) Ltd; 91/335/EEC in case IV/32.186—Cosme-Martell – DMP; and 72/403/EEC in cases IV/26.894, 26.876 and 26.892 — Pittsburgh Corning Europe – Formica Belgium – Hertel, where a fine was imposed on a firm that required its distributors to charge different prices according to the destination of the goods, thereby trying to protect the German market from lower priced parallel imports. More recently, see also the decision of July 14, 1999 in case IV/D-2/34.780 Virgin/British Airways, and the decision 98/273/CE, 28 January 1998, in case IV/35.733 D VW- Audi/Volkswagen, par. 210, where it is stated that “the obstruction of parallel exports of vehicles by final consumers and of cross deliveries within the dealer network hampers the objective of the creation of the common market, a principle of the Treaty, and is already for that reason to be classified as a particularly serious infringement”. At a jurisprudential level, see Consten and Grundig, cit., p. 341; see Miller cit.; Sandoz case, cit.; see 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; and ECJ, ch. III, 6 April 2006, in case C-551/03 General Motors BV v Commission of the European Communities.

38 In the context of Art. 82 EC, such prices could have been considered excessive, because they do not have “reasonable relation to the economic value of the product supplied”, as it was stated by the ECJ in United Brands, cit., at par.250 of the judgement.
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<thead>
<tr>
<th>Product</th>
<th>50 mcg x 200 d.</th>
<th>100 mcg Accuhaler x 60</th>
<th>150 mcg Accuhaler x 60</th>
<th>500 mcg Accuhaler x 60</th>
<th>50 mg (4 compr.)</th>
<th>6 mg inject. (2 jeringas)</th>
<th>100 mg (56 compr.)</th>
<th>25 mg (56 compr.)</th>
<th>50 mg (56 compr.)</th>
<th>200 mg (30 compr.)</th>
<th>25 mg (120 d.)</th>
<th>100 mg Inh. 100 d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beconase</td>
<td>2,15</td>
<td>5,70</td>
<td>2,56</td>
<td>5,08</td>
<td>2,4%</td>
<td>10,8%</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Flixotide 50 mcg</td>
<td>16,13</td>
<td>18,73</td>
<td>21,15</td>
<td>17,20</td>
<td>-</td>
<td>8,1%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Flixotide 250 mcg</td>
<td>53,75</td>
<td>69,99</td>
<td>71,92</td>
<td>57,34</td>
<td>-</td>
<td>22%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Flixotide 100 mcg</td>
<td>32,25</td>
<td>37,46</td>
<td>47,38</td>
<td>35,72</td>
<td>-</td>
<td>4,6%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Flixotide 500 mcg</td>
<td>107,50</td>
<td>139,98</td>
<td>148,92</td>
<td>115,84</td>
<td>-</td>
<td>20,8%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Imigran 50 mg</td>
<td>750,000</td>
<td>825,00</td>
<td>1099,61</td>
<td>790,58</td>
<td>-</td>
<td>4,1%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Imigran 6 mg</td>
<td>2695,50</td>
<td>3752,00</td>
<td>4347,25</td>
<td>3513,87</td>
<td>-</td>
<td>5,6%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lamictal 100 mg</td>
<td>155,36</td>
<td>185,72</td>
<td>232,33</td>
<td>186,98</td>
<td>-</td>
<td>-</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lamictal 25 mg</td>
<td>53,57</td>
<td>74,27</td>
<td>79,19</td>
<td>59,06</td>
<td>-</td>
<td>20,4%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lamictal 50 mg</td>
<td>89,28</td>
<td>107,55</td>
<td>134,68</td>
<td>103,84</td>
<td>-</td>
<td>3,4%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lamictal 200 mg</td>
<td>232,90</td>
<td>245,83</td>
<td>394,92</td>
<td>346,61</td>
<td>-</td>
<td>-</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Serevent 25 mg</td>
<td>34,54</td>
<td>46,95</td>
<td>52,95</td>
<td>35,41</td>
<td>-</td>
<td>32,5%</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Ventolin Inh. 100</td>
<td>1,50</td>
<td>10,00</td>
<td>2,55</td>
<td>2,54</td>
<td>292,1%</td>
<td>293,7%</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
While in some cases new prices applied in Spain for exports still permit trade with UK – assuming that repackaging and shipping costs are negligible – it looks that cross border trade towards other European countries is blocked. It follows that, even if the price scheme implemented by GSK aimed at stopping trade between Spain and UK\textsuperscript{39}, it actually had repercussions over trade within the whole internal market.

Indeed, dual pricing automatically eliminates or drastically reduces the price differential between the low-price country and the high-price country, thereby discouraging intermediaries to enter the importing markets. From this point of view, being an indirect disincentive to trade across the borders, dual pricing has the same effects as an explicit prohibition to export\textsuperscript{40}.

The objective of impeding parallel trade can be achieved not only by direct restrictions on exports but also through indirect measures, like those that influence the economic conditions of transactions\textsuperscript{41}. In fact, a pricing policy that renders intrastate trade economically uninteresting is even more effective than an explicit export ban, as it does not entail the establishment of monitoring devices\textsuperscript{42}.

By applying a higher price for goods intended for export, the manufacturer \textit{de}

\textsuperscript{39} See the Commission decision on GlaxoWellcome, cit., par. 22, where it is reported what GSK declared in a response of 6 May 1998 to the Commission: “... in practice, the principal immediate effect [Clause 4] will be on trade between Spain and the UK, as the greater part of Spanish-sourced parallel imports are sold on the market in the UK”.

\textsuperscript{40} Similarly, see Moët et Chandon, cit., where the Commission qualified a clause which established a price list for champagne valid only for consumption in United Kingdom but not for consumption outside that territory, as a restriction by object; Gosme-Martell, cit., where the Commission found that the elimination of the usual discount system applied to customers by the manufacturer \textit{de facto} rendered export more expensive and equated it to an export ban; similarly, see in particular, Pittsburgh Corning Europe, cit., the increase of Belgian wholesale prices of 40% aimed at impeding re-importation into Germany was considered to be anticompetitive by the Commission, which explicitly drew up an analogy between export bans and dual pricing systems, having the former the same effects as the latter on parallel trade.

\textsuperscript{41} From this point of view there is a clear parallelism – not mentioned by the CFI - between the Glaxo case and the previous Sandoz case. In that occasion, the ECJ established that sending invoices to wholesalers with the wording ‘export prohibited’ constitutes a vertical agreement capable of hindering competition under Art. 81 EC. See Sandoz, cit., par. 13, and also ECJ, 15 July 1970, in case C-41/69, ACF Chemiefarma NV v Commission of the European Communities, par. 12.

\textsuperscript{42} Similarly, in Distillers, cit., the Commission considered the non-applicability of price allowances on spirits for export and the application to the same customers of different prices for spirits for export and for spirits for United Kingdom consumption a more efficient way to discourage export than direct export bans. See point 2 of the cited decision.


facto raises its competitors’ costs. In fact, the price at which Spanish wholesalers purchase products from the manufacturer constitutes their marginal cost (provided that repackaging and shipping costs are negligible). The higher price applied to exports by GSK increases this marginal cost up to a point where export is economically less interesting or impossible.

As a result, intermediaries lose their price advantage necessary to penetrate the foreign market, and the manufacturer ensures that no competitor having lower costs enters the importing markets, thereby contending its market share.

This, on the one hand, restricts the economic opportunities available to other agents as a result of the establishment of the European common market, whereas, on the other hand, it allows the manufacturer to seal off the market of origin for exports (Spain) and to protect the destination markets. These markets cover the whole Community.

In the European context, these effects clearly represent a concern. Dual pricing, in fact, restores trade barriers along national borders, thereby holding up the economic interpenetration that the Treaty intended to bring about. In other words, it frustrates the policy goal of integration internal market, which still constitutes one of the ‘constitutional’ objectives of the Community.

2.2. Harmonisation of prices v. price discrimination

From a legal point of view, one could observe that, even pursuing the policy goal of market integration for pharmaceuticals, competition through parallel trade is not necessarily the principal instrument deemed to achieve it, especially known that Member States are willing to retain their competence on price regulation, and that the Treaty provides European Institutions with other means to achieve harmonisation.

From an economic point of view, however, the issue of integration of the European pharmaceutical market takes a different nuance. The relevant question is

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43 From this point of view, dual pricing can represent a preferable alternative to price war, as it has the advantage of avoiding profit reduction and sacrifice of financial resources. See SALOP and SCHEFFMAN, Raising Rivals’ Cost, The American Economic Review, Vol. 73, No. 2, (1983), pp. 267-271.

44 See the ECJ in the Bayer case, cit., at par. 179: “it is not open to the Commission to attempt to achieve a result, such as the harmonisation of prices in the medicinal products market, by enlarging or straining the scope of the Section 1 (Rules applying to undertakings) of Chapter I of Title VI of the Treaty gives the Commission the specific means of seeking such harmonisation where it is undisputed that large disparities in the prices of medicinal products in the Member States are engendered by the differences existing between the state mechanisms for fixing prices and the rules for reimbursement as is the case here.”

45 See REY, VENIT, Parallel trade and pharmaceuticals: a policy in search for itself, Eur. L.R., 2004, no. 29, p. 173, who argue that under the Treaty, the “harmonisation” measures identified by Art. 95(3) are to be adopted according to the procedure set forth by Art. 251.
rather whether the goals of equitable access, cost containment and improved efficiency, identified in the literature as the main objectives to be achieved in regulation of pharmaceuticals\textsuperscript{46}, can be better achieved through price harmonization or by allowing price discrimination.

On the one hand, harmonisation could promote equal access to drugs from consumers in all Member States. Conversely, geographical price discrimination, and those practices that foster it, like dual pricing, could pose distributional and fairness concerns\textsuperscript{47}.

On the other hand, if it results in an increase in output, also price discrimination can be beneficial in terms of allocative efficiency. This pricing rule, indeed, minimises the reduction in consumption that would result from charging uniform prices above marginal costs to all consumers. By charging lower prices to patients with higher price elasticity, output can be expanded and welfare loss decreased\textsuperscript{48}. This is particularly important in the case of pharmaceuticals, where the policy goal of facilitating access to medicines for patients is a major public interest at a European level\textsuperscript{49}.

At the same time, efficiency concerns induce to affirm that, given the necessity for pharmaceutical companies to recoup their large sunk investments in R&D, it is fair to let each country contribute to these costs in proportion to their ability to pay\textsuperscript{50}. Such contribution is reflected in the domestic price accepted by the national authority.


\textsuperscript{47} In light of Art. 6 EC, discrimination on the basis of nationality is often seen as contrary to the spirit of the Treaty by the ECJ.

\textsuperscript{48} The theory, however, contrasts with the fact that new accession countries, for instance, experience higher prices than some old Member States, although their purchasing power is knowingly lower.

\textsuperscript{49} See Commission Communication COM(1998) 588 final, where it is said that it would be extremely difficult to establish an appropriate level of price across the Community, as the choice of a low level would benefit immediate health care expenditure objectives but would provide a steady diminution of Europe’s contribution to global pharmaceutical R&D investment, and the choice of a high level would have the effect of reducing access to care by consumers and payers in countries where economic and social conditions mean that such prices cannot be afforded (p. 11). See also Danzon and Tows, Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents, in International Journal of Health Care Finance and Economics, 2003, no. 3, p. 183–205; see Danzon, Wang and Wang, The impact of price regulation on the launch delay of new drugs - evidence from twenty-five major markets in the 1990s, in Health Econ., 2005, no. 14, p. 269–292.

\textsuperscript{50} See Glynn, Article 82 and Price Discrimination in Patented Pharmaceuticals: the Economics, in ECLR, 2005, vol. 26, no. 3, p. 139. See also Whish, Competition Law, cit., p. 511, who says that political, cultural and economic differences among Member States could justify price discrimination. See also the Progress Report and Draft Conclusions of the High Level Forum on Pharmaceuticals on http://ec.europa.eu/enterprise/phabiocom/comp_pf_mtg_20070626.htm, where it is said that “it has also
Nonetheless, as already pointed out, it should be considered that domestic prices do not mirror the internal economic conditions within a given country only. In fact, they often incorporate the result of an international price comparison with other countries, applied either through reference price systems, either through parallel trade itself.

Apart from any evaluation of effectiveness of such strategies in containing pharmaceutical expenditures\(^5\), they represent a signal of the fact that, even if eager to contribute to research, governments feel that drug prices are often too high with respect to their degree of innovation.

Ideally governments accept high prices for innovative drugs\(^5\), while they apply more strongly cost containment policies for old drugs. Nevertheless, it is often observed that new medicines tend to have a price mark-up over existing comparable alternatives, both when a higher price can be justified as a reward for a product that represents a real innovation, and when these new drugs have similar therapeutic effects to those already on the market (so called ‘me-toos’\(^5\)).

It follows that the large price differentials observed among European countries does not appear always economically justified and that a certain degree of harmonization for prices of medicines with the same therapeutic characteristics of other pharmaceutical products already existing in the market is needed in order to fulfil the goal of cost containment. Health care finances are in fact limited, and efficiency also requires that patients get value for what they spend.

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\(^5\) See critics of the efficacy of this strategy in the long term from an economic point of view in Garrison and Towse, The Silo Drug Budget Mentality in Europe, Value in Health, vol. 6, no. 1, 2003; Atella, Drug cost containment policies in Italy: are they really effective in the long run? The case of minimum reference price, Health Policy, 2000, no. 50, p. 197 – 218.

\(^5\) National coverage policies follow that so-called ‘three hurdles’ criterion: authorities reimburse drugs whose safety, quality, and efficacy are proved. However, reimbursement can also be used as a means of rewarding innovation, with new products judged to be clinically valuable receiving premium prices. That is why along with the previously mentioned criteria, national authorities are now also developing a fourth and a fifth hurdle: the requirement of clinical effectiveness and cost-effectiveness of a drug.

\(^5\) See Mossialos, An overview of pharmaceutical policy in four countries: France, Germany, the Netherlands and the United Kingdom, International Journal of Health Planning and Management, 2005. Similarly in the report of the Office of Fair Trading on the reform of the PPRS scheme (Pharmaceutical Pricing Regulation Scheme, the scheme used by the British regulator to control the increase in pharmaceutical prices) published in February 2007, it is said that products with similar therapeutic effects are often unreasonably reimbursed at different levels. See http://www.oft.gov.uk/News/Press+releases/2007/29-07.htm.
Given the importance of this threefold aspect of pharmaceutical regulation, it looks essential in the welfare analysis to study the effects of dual pricing on access to medicines from patients, on cost governments’ containment strategies and on improved efficiency of the industry.

3. **Dual pricing and the equitable access to medicines for patients**

Generally the hypothesis that an agreement has restrictive effects on competition should be verified by checking the effect that such agreement has on price and quantity at which the product is sold\(^\text{54}\). The dual pricing system seems to influence both.

3.1. **The effect of dual pricing on medicine supply availability**

Let us consider a setting where the manufacturer markets a pharmaceutical product in two different countries. The manufacturer freely sets its price in one country only, whereas in the other country drug prices are subject to governmental regulation. That is, for a given drug, the manufacturer charges a monopolistic price \(p\) that maximises its profit, based on the demand existing for that drug in the high-price country, but it has to bargain with the government in the low-priced country a fixed price \(\bar{p}\), assumed to be lower than \(p\).

The deriving price differential \(p - \bar{p}\) creates scope for parallel import, as long as shipping costs are lower than such price disparity. In other words, I consider parallel trade as the result of price differentials caused both by manufacturers’ pricing policies and governmental price controls\(^\text{55}\).

The parallel importer, in order to contend the market to the manufacturer in the importing country, sets a price equal to \(p_{pt} = p - \varepsilon\).

In this setting it is assumed that there are no capacity constraints for the manufacturer and for the parallel trader, neither related to the production system.

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\(^{54}\) See Glaxo, cit., par. 167, where it is acknowledged that art. 81 is an important tool that was construed in order to pursue the establishment of the internal market and the granting of effective competition within the latter.\(^{55}\) According to the literature parallel trade emerges either because of the possibility for arbitrageurs to free ride on the investments of authorized distributors at various levels of the distribution chain, either because of the occurrence of price differentials. This latter circumstance is entailed by currency exchange, international price discrimination policies from manufacturers or price control mechanisms from governments, as in the case of pharmaceuticals. Following PECORINO, *Should the US allow prescription drug reimports from Canada?*, Department of Economics, Finance and Legal Studies, University of Alabama, 2002; GROSSMAN and LAI, *Parallel Imports and Price Controls*, 2006; MATTECCI and REVERBERI, *Price Regulation and Public Service Obligations under International Arbitrage*, in *Journal of Regulatory Economics*; 28:1 91-113, 2005; SAUER, *A Model of Parallel Imports of Pharmaceuticals with Endogenous Price Controls*, University of Colorado at Boulder, 2005, this paper investigates the ‘price control-hypothesis’.
characterising the industry, nor of a strategic nature. In other words, it is assumed that the manufacturer does not apply supply management strategies, i.e. it does not put quotas on wholesalers in the low-price country. Nevertheless, the flow of parallel trade cannot be potentially unlimited, as wholesalers in the exporting countries are obliged to serve the domestic market first. A strict application of the EU legal provisions on uninterrupted supplies could justify all these assumptions\textsuperscript{56}.

It is further assumed that parallel traded products are imperfect substitutes of the original ones\textsuperscript{57}. This, for non-reimbursed products, means that only patients with a lower willingness to pay will turn to cheaper products\textsuperscript{58}.

It follows that parallel imports’ penetration in the destination market does not come at the expenses of all the sales of the manufacturer, but it yields a reduction in its sale volumes of an amount \(\alpha\). While \(\alpha\) gives a measure of the percentage of patients actually turning to parallel imports, \((1 - \alpha)\) is the percentage of people that will continue to buy from the manufacturer.

In the case of reimbursed products, \(\alpha\) could capture the ‘receptiveness’ of the health care system in the destination market to cheaper products. Such openness is given by the incentives put by the health care system on relevant agents\textsuperscript{59}. Physicians

\textsuperscript{56} See the Art. 81 of so-called ‘Human Use directive’, Dir. 2001/83/EC, as amended by the Dir. 2004/27/EC of 31 March 2004, which states: “The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition”. In this respect the pharmaceutical market presents very different features with respect to other sectors, where the withdrawal of a product is always possible and it actually occurred, as a consequence of parallel trade. An emblematic case is the Distiller case, (see EC Commission 78/163/EEC in case IV/28.282 — The Distillers Company Limited — Conditions of sales and price) where the company, after the Commission’s prohibition to hinder re-importation of its Scotch whisky in the UK market, it withdrew the product from the other EU countries. See KORAH, Goodbye, Red Label: Condemnation of Dual Pricing by Distillers, Eur. L. R., 1978, no. 3 , p. 624.

\textsuperscript{57} The activity of re-packaging and applications of stickers and windows that, according to national and European legislation, allow to brands and marketing authorisation owners’ names to remain visible and at the same time to give information to patients, can render packs very different from the original ones, so that consumers perceive the good as a different one, i.e. of a lower quality.

\textsuperscript{58} The reference here is necessarily to OTCs and I do not consider private insurances aimed at covering health care expenditures. In the latter case patients’ sensitivity to price changes depends on their insurance coverage. Anyway, the degree of coverage could be expressed again by \(\alpha\).

\textsuperscript{59} It should be noted that large part of the literature, however, argues that both consumers and physicians are poorly informed on drug prices and follow heuristic approaches to choose drugs, and that they are sensitive more to out-of-pocket cost share, or ‘generosity of coverage’ than to price. See O’BRIEN, The effect of patient charges on the utilization of prescription medications, Journal of Health Economics, 1989; VAN VLIET, Effects of price and deductibles on medical care demand, estimated from survey data, Applied Economics, 2001; ROSENTHAL, BERNDT, DONOHUE, Demand effects of recent changes in prescription drug promotion, Kaiser Family
play a key role in this respect: in fact, if subject to adequate financial incentives, they should react to the presence of cheaper products in the market by prescribing the drug in its parallel traded version rather than the branded one.

However, the actual portion of population consuming parallel traded drugs is determined by the concrete availability of these products in the pharmacies. In turn, access to lower-priced products is determined by the incentives of pharmacists to seek for cheaper supplies. An illustrative example at this regard is given by the ‘claw-back’ system implemented in UK by the NHS to take into account the savings which all UK pharmacists together achieve each year by placing orders with parallel traders. Every pharmacist faces the same claw back, irrespective of whether or not he actually dispenses parallel traded products or, if he does, whether or not his savings correspond to the claw back figure. Although this mechanism might aim primarily at avoiding unjust enrichment by intermediaries and pharmacists, it also encourages them to turn to parallel traders. If they purchase drugs via parallel trade in the same amount of the claw back figure, they are indeed better off than competitors whose purchase of parallel-traded drugs are below that level or who even buy all their requirements domestically.

Always assuming absence of supplies’ bottlenecks, it is possible to envisage an additional demand segment nourished by parallel trade, and composed by those patients who were not served by the manufacturer.

In the case of non-reimbursed pharmaceutical products, this demand segment consists of those consumers whose willingness to pay is lower than the price practiced by the manufacturer.


60 In the Netherlands, for instance, pharmacists who find cheaper products via parallel imports do not have to inform the Dutch health ministry and receive the same fee. This increases their profit margin and thus gives them an incentive to engage in parallel trade. In Denmark, pharmacists have a legal obligation to inform the patient about all available cheaper substitutes, including parallel traded products. Also in Germany and Sweden, pharmacists are encouraged to use parallel imported goods. According to a 1999 report by the Swedish competition authority, counties recommend that pharmacies sell the cheapest medicine, including parallel products. In Germany, pursuant to amended paragraph 129 of the Social Security Act (Sozialgesetzbuch), pharmacists are also obliged to sell cheap imported pharmaceutical products in circumstances which will have to be spelled out in a contract between the pharmacies and the health insurance companies ‘Krankenkassen’ (‘Re-Import Förderklausel’, re-importation promotion clause).

61 The NHS automatically deducts from the manufacturer’s list price a discount (the ‘claw back’) in the range of 4% to 5%. The claw back mechanism aims at ensuring that these savings are at least partially transferred to the NHS (and to taxpayers).

62 The result is a market segmentation allowing vertical price discrimination that overall can increase the volume sold by the manufacturer. See Ahmadi and Yang, Parallel Imports: challenges from unauthorised Distribution Channels, cit., p. 286, for discussion of the circumstances when also profits increase, and Kyle,
In the case of reimbursed drugs, the demand segment is composed by the patients to whom the physician did not prescribe the drug before the appearance of its lowered price version in the market. A cheaper price, in fact, changes the cost-effectiveness ratio of a drug, thereby rendering financially sustainable to start prescribing that drug also to patients who before were not treated. In other words, given the price of a drug, one can identify a critical threshold in the level of risk that a patient with certain symptoms develops a chronic disease, above which it is considered cost-effective to treat those symptoms with that drug. When the latter is available at a lower price, the critical threshold drops in value. As a result, more people who were not treated before, or who were treated with another drug, receive the treatment.

In general, parallel imports’ penetration appears to entail a boost in the demand for drugs subject to importation in the destination countries. The appearance of this new demand portion cannot be considered artificial. In fact, the negotiation with trade partners other than the traditional ones implies additional transaction costs. Wholesalers and pharmacists are willing to bear such costs only as long as there is a benefit from it. Such a benefit can be identified in the fact that parallel trade offers some advantages in terms of price or availability of supplies. It follows that this alternative distribution system subsists insofar it meets the needs of an existing demand.

This is not surprising, as, when different consumers are charged different prices, there are likely to be some consumers in the high-price group who would be willing to pay what the low-priced group pays but not what the high-priced group pays. This will cause that some consumers in the high-priced group will not buy the good, whereas others in the low-priced group, who value the product less, buy it. Static welfare would be improved if the marginal unit of good bought in the low-price country is instead bought in the high-price country, where the evaluation of that unit is likely to be higher. This result can be achieved through international trade.

Clearly, dual pricing has the effect to suppress gains from trade in the first place. In fact, the additional segment of the demand opened up by parallel trade is not (totally) served if dual pricing is in place.

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Strategic Responses to Parallel Trade, NBER Working Papers no. 12968, 2007, for similar conclusions. The same result was previously found by GERTNER and HOLTHAUSEN, Profitable pricing when market segments overlap, 5(1) Marketing science, (1986), pp. 55-69, and SIMON and KUCHER, The European pricing time bomb, cit., pp. 140.

See RIDYARD, Exclusionary pricing, cit., p. 286; see also BISHOP, WALKER, The Economics of EC Competition Law, cit., p. 197.
It follows that the restriction produced by dual pricing is given by the reduced availability of products in the importing markets. Accordingly, access to medicines is restricted, since consumers cannot benefit from the greater availability of products provided for by parallel trade.

3.2. The effects on prices: the intrabrand competition

While a pharmaceutical product is in patent, price competition works only to a limited extent.

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 system, either by private insurance. 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’64) and unable to choose among different therapies, they have to rely on the expertise of a physician. Substitution through cheaper products, hence, depends in the first place on the economic incentives to which the doctor is subject to.

Secondly, substitution among pharmaceutical products is based on the ATC (Anatomical Therapeutic Classification) classification, which groups the pharmaceutical specialties into therapeutical classes65. Substitutability among medicinal products is in fact determined by the therapeutical properties of products rather than by the pharmaceutical form (pills, solutions, etc.) or 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 be a set of therapeutical alternatives, are not perfect substitutes, as the replacement of a drug

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64 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.

65 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.
with another 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 pharmaceuticals products. 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 cheaper product, the pharmacist is bound to supply the branded product by the legislation of several Members States. He cannot offer an alternative product even though it may be pharmacetically equivalent\textsuperscript{66}.

Such a product differentiation is enhanced by the fact that some drugs have been developed to cure only a particular disease. This makes so that product markets 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 small number of companies having such resources to enter a potential market on one hand, and the patent protection provided for by the system on the other, reduce the possibilities of penetration of the market from new entrants, especially if they are not endowed with sufficient financial resources.

These characteristics show that interbrand competition can exert a poor pressure on prices during patent validity, thereby allowing companies to have a certain influence over the price of their medicinal specialties. That is why the stimulus of intrabrand competition, provided for by parallel trade, appears to be essential in this context.

Indeed, parallel traded 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 helps in surmounting therapeutical substitution problems, for instance by allowing access to a particular medicine from patients who for physical constraints are bound to take that drug, while realising cost containment policy goals at the same time.

\textsuperscript{66} See LUCIONI, Economia e normativa del farmaco, 1998.
From this it should follow that dual pricing, by hindering parallel trade, restrains *intrabrand* competition, thereby impeding consumers to enjoy a wider access to medicines and governments to implement their cost containment strategies through lower prices.

Nevertheless, despite a prior acknowledgment of the positive effect on prices exercised by parallel trade\(^{67}\), the Court subsequently affirmed that it is impossible to presume in principle that parallel trade on pharmaceuticals brings the above-described benefits, because of the regulation on prices that characterises the pharmaceutical market.

In the view of the Court it appears, firstly, that ‘prices are finally set by Member States’; secondly, that ‘prices falls outside the play of supply and demand’; thirdly, that they are ‘established at structurally different levels throughout the Community’. This, in the view of the Court, could be sufficient to impede the occurrence of the competitive pressure traditionally associated to parallel trade.

Consequently, the anticompetitiveness of vertical agreements in the pharmaceutical sector should be carefully analysed in light of the specific features that characterise this market. Such specificity is identified exactly with the fact that prices are regulated differently across Europe.

4. **Is the pharmaceutical market specific?**

In principle, 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 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\(^{68}\). Lacking harmonisation, in fact, it is normal that domestic and export sales are subject to different regulations, albeit this does not modify the anticompetitive features of an agreement\(^{69}\).

\(^{67}\) See *Glaxo*, cit., par. 107, 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.

\(^{68}\) “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...”. See *Merck v Primecrown*, cit.

\(^{69}\) See *General Motors Nederland BV*, cit.
This seems to be supported by the fact that there are many other sectors - like utilities, fuels and gasoline, tobaccos, books - where prices are regulated in different ways and differ from State to State, without that this constitutes a reason to claim a departure from the traditional judgement of anticompetitiveness of an agreement, due to the specificity of the sector.

From an economic point of view, 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, negotiated prices are only maximum prices, which do not impede to have lower price in the market through competition at the retail level\textsuperscript{70}.

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 one hand, should improve access to medicines and, on the other, relieve public finances.

The empirical evidence provided for by the Commission, and subsequently accredited by the Court itself, confirms this. Indeed, in the Glaxo case the Commission 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\textsuperscript{71}. In a context where national health systems are considered final consumers\textsuperscript{72}, the mentioned measures show then that parallel trade is capable of bringing about benefits.

Such benefits are both direct and indirect. Direct benefits derive from the lower prices paid by patients that purchased parallel imported products, which in turn entail

\textsuperscript{70} See ABBOTT, Price regulation in the pharmaceutical industry: prescription or placebo?, in J Health Econ., n. 14, 1995, 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.

\textsuperscript{71} See the Commission decision in the GlaxoWellcome case, cit., par. 48-52.

\textsuperscript{72} 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.
lower reimbursement costs for health care systems and lower premium for health insurance. The indirect benefits derive from the competitive pressure put on manufacturers by parallel importers that drives down patented products prices, or decelerates their increase\textsuperscript{73}. An illustrative example of dynamic effect of \textit{intrabrand} competition is given by the following graph:

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{graph.png}
\caption{Illustrative example of dynamic effect of \textit{intrabrand} competition.}
\end{figure}

\textsuperscript{73} Some empirical studies attempted to quantify such effects but found contradictory evidence at this regard. See West, Mahon, \textit{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. Contrarily, Kanavos, Costa-i-Font, Merkur, Gemmill, \textit{The Economic Impact of Pharmaceutical Parallel Trade – A Stakeholder Analysis}, LSE, 2004, found little competitive effect and a very small price reduction for on-patent drugs subject to parallel import. The most recent study on this subject, Pedersen et al., \textit{The Economic Impact of Parallel Import on Pharmaceuticals}, 2006, provided counterarguments to the findings of the LSE 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, the United Kingdom and Sweden. 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. See also Ganslandt and Maskus, \textit{Parallel Imports of Pharmaceutical Products in the European Union}, World Bank Policy Research Working paper No. 2630, 2001, providing empirical evidence, collected in Sweden between 1995 and 1998, that to an increase of parallel import activities corresponded a decrease of home market prices or a diminution of the increase in prices. Roughly three-fourths of this effect was attributed to the lower prices of parallel imports and one-fourth to lower prices charged by the manufacturing firm.
Table 2: dynamic gains from intrabrand competition

<table>
<thead>
<tr>
<th>Month</th>
<th>Price 1</th>
<th>Price 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td></td>
<td></td>
</tr>
<tr>
<td>February</td>
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<td>March</td>
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<td>April</td>
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<td>July</td>
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<td>August</td>
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<tr>
<td>September</td>
<td></td>
<td></td>
</tr>
<tr>
<td>October</td>
<td></td>
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</tr>
</tbody>
</table>

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

Clearly, actual effects on prices are affected from regulation present in the importing country. For instance, in UK pressure on prices cannot be measured monthly nor yearly, but only every five years, as pharmaceutical prices are subject to the pharmaceutical price regulation scheme (PPRS) scheme. 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. 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, as the following graph shows:

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74 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, b) restriction or suspension of price increases requested by the manufacturer; repayment of excessive profits.
Table 3: matching between a reduction in parallel trade activities in UK and price reductions at the renegotiation of the PPRS in 2005.

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

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

In light of the above, the relevant question 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.

Sticking to our framework where we assume that manufacturers do not implement supply management strategies\(^75\), one can find that the level and the distribution of savings and the consequent welfare effect brought about by parallel trade depends on the degree of wholesale and retail competition present in the importing

\(^75\) On the contrary, 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 also PEDERSEN ET AL., The Economic Impact of Parallel Import on Pharmaceuticals, cit.
market. The latter is necessarily influenced by the economic characteristics of the industry and especially by regulatory constraints.

For instance, while a maximum price set by the authorities makes economic sense, as it 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\textsuperscript{76}. Often pharmaceutical companies do not lower down their domestic prices in response to competition, as this would have had 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 parallel trade\textsuperscript{77}.

Price controls mechanisms are also a regulatory tool that appears to distort competition. Drug prices formation, in fact, departs from the classical functioning of a perfect market, where the market-clearing price is the result of the encounter of demand and supply. On the contrary, prices seem to be governed by the continuous interaction between public health protection and public expenditures containment goals and the economic interest of companies. As a consequence, pricing in the pharmaceutical sector does not follow a competitive process.

However, price bargaining procedures could display a potentially helpful device to foster competition.

4.1. The effect of price controls on competition: a bargaining model

While it is true that price controls head off from competition, it is also true that distortions come in the first place from the market failures that characterise this sector and render necessary from the economic point of view the regulatory intervention\textsuperscript{78}.

\textsuperscript{76} In Italy, for example, it has been observed the absence of any kind of price competition bringing prices below the reference point. See the report from the Italian Competition Authority AS131/1998 “Determinazione del prezzo dei farmaci” and 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.

\textsuperscript{77} 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.

\textsuperscript{78} 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, there are concerns over national drug pricing policies, which often limited
The fact that pharmaceuticals are merit goods, 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 has to be granted by the State, through consumption’s financing.

As already explained, the reimbursement system creates a departure from classical market functioning: the classical consumer choice theory does not apply to pharmaceuticals, as the patients uses a product that an agent – the physician – chooses on his/her behalf and that the government pays for him/her.

The inelasticity of demand deriving from this trilateral relationship, consequently justifies from an economic point of view the use of buyer power from health authorities in price negotiations. Indeed, it makes economic sense that a public body, ideally able to better judge the properties of these products and to associate an adequate price to them, is the more appropriate entity to pursue objective of allocative efficiency when the market alone is not capable.

The bargaining process on prices between regulators and companies in fact can achieve a twofold outcome: on 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.

When parallel trade takes place in equilibrium, the bargaining procedure could

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79 The governmental intervention in the financing of drug consumption is economically justified by the fact that pharmaceuticals are ‘merit good’. Merit goods are goods 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”.

80 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.

81 See Capri and Levaggi, Reconciling social and industrial goals: a bargaining model to pricing pharmaceuticals, Liuc working paper Economia e Impresa 42, 2005.
display even more potentials from this point of view. The threat of parallel trade, in fact, gives bargaining power to authorities and insurance funds vis-à-vis the companies in price negotiations for domestic products. Especially in those markets where cost containment strategies are implemented, 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\textsuperscript{82}.

Let us take the health authority in the high-price country, market target of the exports coming from the low-price country shipped by the parallel trader. In principle, parts of the pharmaceuticals consumed and reimbursed in the high-price country will come from the cheaper parallel channel, directly entailing savings to part of the population and to the health care system, as long as they are reimbursed. At the same time, the parallel trader will make a profit out of this deal, while the manufacturer will make a loss.

In this situation, price negotiation in the high-price country can take a new dynamic. By the mean of the reimbursement system, the health authority (or the insurance fund) has the power to govern all sales within 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\textsuperscript{83}: 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. An example could better clarify this concept.

The manufacturer sells 100 units at 0.50 Euros in the low-price country and 50 units at 1 Euro in the high-price country. The parallel trader acquires in the low-price country 50 of the 100 units, thereby spending 25 Euros, and ships them from the low-price country to the high-price country for a price of 0.80 Euros, thereby earning a revenue of 40 Euros and a net profit of 15 Euros. The purchaser in the high-price country in total spends 90 Euros. The manufacturer loses 25 Euros (by loosing the chance to sell

\textsuperscript{82} See CAPRI, LEVACCI, Reconciling social and industrial goals, cit.

\textsuperscript{83} From this example a bargaining model could be implemented. The literature of reference for this purpose could be 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.
directly the extra-50 units at 1 Euro to the low-price country, where evidently there is a demand for a larger quantity of products, and letting the trader sell them). So, in the high-price country he earns 50 Euros instead of 75 Euros. However, the purchaser can propose to the manufacturer to lower down its prices, say to 0,825 Euros, so that they both gain: the manufacturer now earns 82,5 Euros, thereby recouping 7,5 Euros, and the purchaser saves 7,5 Euros, thereby spending 82,5 Euros in total instead of 90 Euros.

4. **Does dual pricing improve efficiency?**

Art. 81(3) EC provides for the possibility that an agreement restrictive of competition, is exempted from the application of Art. 81(1) provided that it brings about some benefits.

In particular, an agreement should: 1) contribute to the improvement of the production or distribution system or to the promotion of technical and economic progress; 2) be such that also consumers equally benefit from the economic advantages; 3) not impose to involved undertakings restrictions that are not indispensable to the achievement of this goal; 4) not allow the undertaking to completely eliminate competition in a substantial part of the market.

According to European case law, such benefits must be in the first place appreciable in an objective way and such that they compensate the detriment to competition (so called balancing exercise)\(^{84}\). In this way companies can demonstrate that the restriction was necessary\(^{85}\). Furthermore, the existence of such benefits has to be proven convincingly and supported by robust evidence\(^{86}\). Finally, between the efficiency gains and the agreement there must be a causal link, whose evidence must be direct and effective\(^{87}\), and proved by the party who claim the existence\(^{88}\).

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\(^{84}\) See *Consten and Grundig cit.*, par. 348 e 349; CFI, II sez. II enlarged composition, 8 June 1995, in case T-7/93 Langnese Iglo GmbH v Commission of the European Communities, par. 180; ECJ, 29 October 1980, in case C-209/78, Van Landewyck SARL and Others v Commission of the European Communities, par. 139.

\(^{85}\) See *Consten and Grundig cit.*, par. 348.

\(^{86}\) See ECJ, 17 January 1984, in joint cases C-43/82 e C-63/82 VBV and VBVB v Commission of the European Communities, par. 52; ECJ, V ch., 7 January 2004, in joint cases C-204/00, C-205/00, C-211/00, C-213/00, C-217/00 and C-219/00 Aalborg Portland and Others v Commission of the European Communities, par. 78.


\(^{88}\) See ECJ, V ch., 11 July 1985, in case C-42/84 Remia BV v Commission of the European Communities, par. 45; see also art. 2 of Reg. (EC) 1/2003 of 16 December 2002, which establishes that the burden of proof in the context of art. 81(3) is on the party that claims the exemption.
With regards to the first condition necessary to obtain the exemption, the achievement of technical and economic progress, and the improvement the productive and distributional system, GSK said that dual pricing contributed to technical progress, by increasing the resources to be spent in R&D, and the efficiency of the distribution, by impeding the diversion of products from their traditional distribution channels.

The pharmaceutical industry is based on large investments in innovation, which is the principal factor determining the competitiveness of a company in the sector. This renders necessary to recoup these costs through a constant and consistent flow of profits, in order to grant that the company keep in the long run its incentive to invest in research to discover new drugs. Therefore, dual pricing, by eliminating parallel trade and profit losses ensures to GSK the possibility to fully benefit of the monetary value of its patent, thereby stimulating research and promoting dynamic efficiency and consumers’ welfare.

At this regard, the Court thought that the Commission, in denying the exemption from the application of art. 81 EC, did not sufficiently considered all the economic aspects of the case, especially with regards to the possibility that the extra-profits entailed by dual pricing could have translated into larger investments in R&D.

5.1. The causality link

At this regard, the main issue here appears to be whether the balancing exercise provided for by Art. 81(3) EC is backward looking or forward looking: in the former case, damage suffered by consumers due to restriction of competition should be weighed against the actual and current benefits entailed by the agreement; in the latter case, the benefits to be considered should be projected in a long term perspective, which inevitably forces the reasoning to be in terms of probability.

The forward looking reasoning should be translated in the following balancing exercise from the judge: the extra-profit gained from dual pricing should lead the company to arrive earlier to the innovation; by the development of a new molecule, which should be more effective than the previous ones having similar therapeutic effects, governments should save a certain amount of money. This amount has to be

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90 See Glaxo, cit., par. 301-303.
weighed with the lost savings that would have been realised by permitting parallel trade until the later moment of discovery of the new molecule.

From the purely legal point of view, however, this standard of proof does not find support. Previous case law clearly established that the request of exemption could not be justified on the basis of something that can possibly happen; on the contrary, technical progress should be objectively appreciable. In other words, it is necessary to prove the certainty of a causal nexus between the agreement and the efficiency gains and not only the possibility.

The reduction to the simple likelihood of the existence of a causality link between the agreement and the efficiency gains, in fact, would dangerously imply that any restriction to competition that allows diversion of revenue from ‘non innovative stakeholders’ (like consumers) to ‘innovative firms’, like a cartel, is presumed to entail an improvement in innovation and on this basis should be exempted under art. 81(3).

In order to justify the implementation of such system of prices, it is necessary to prove the existence of a direct relationship between parallel trade and the reduction of investments in research, as well as the diminution of the number of molecules in the market.

However, given the long period necessary (10-15 years) to develop new molecules and to bring them onto the market, and given the articulated and complex regulatory context like the pharmaceutical one, it appears difficult to single out a relationship deprived of any interference between parallel trade and an eventual reduced number of molecules in the market. Indeed, because of the long time necessary, the reasons that could have led to a lower amount of resources devolved to research can be manifold: for instance, the ‘domino effect’ of the reference pricing is capable of reducing profits not only in a European market but also at a global level. Moreover, the expiration of one or more patents and the subsequent penetration of the market from generics induce companies to lower its prices in order to sustain competition, thereby reducing its profits.

Therefore, not only parallel trade cannot be the only determinant of the rate of discovery of new drugs, but also, as GSK itself admitted, it is not even the main factor.
conditioning the companies’ choices of investment in R&D. There are other factors that have greater influence in such decisions: the expected profitability of a product, the rate of interest, exchange rate fluctuation, uncertainty of demand etc.

5.2. Does more money mean more innovation?

In addition, demonstrating that with more resources at its disposal GSK would invest more in R&D does not equal to show that dual pricing increase dynamic efficiency. In fact more profits does not equal to more innovation.

The innovative process is subject to uncertainty and success is merely probabilistic and strongly based on the business model\(^{94}\). This seems to be confirmed by recent studies that show how industry in the last ten years increased investments in innovation without succeeding in improving the slow rate of discovery of new molecules.\(^{95}\)

It follows that from an economic point of view it seems more appropriate to affirm that the amount of resources devoted to R&D from a pharmaceutical company does not depend exclusively on profits earned but rather on how much innovation is necessary to remain competitive on the market.

In the specific case, GSK declared to spend the 23% of its turnover on sales expenditures, the 33% in administrative costs and the 14% in R&D, being left with 30% of this turnover as a net profit before tax\(^{96}\). With such a large amount of money, it is logical to think that GSK considered already optimal for its competitiveness to spend the 14% of its budget in research, and that, in case it wanted to increase this percentage, nothing, neither parallel trade, could have prevented it to do so. Indeed, if confronted with the entire budget of a multinational firm operating at a global level, it is clear that losses caused by parallel trade are relatively small and incapable of creating real financial problems.

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\(^{94}\) See Pisano, Science Business, Harvard Business School Press, 14 November 2006, where it is affirmed that the pharmaceutical industry needs a new financing model. Big multinationals provided most of the innovation, but different factors like lower share prices, generics penetration, bureaucracy due to mergers realised in the last ten years, blocked the incentive to innovation. For the time being, research productivity and the number of marketing authorizations are declining. Consequently, pharmaceutical companies became risk averse, and preferred to develop so called “me too drugs”, namely imitations of medicines already present in the market.

\(^{95}\) See Could a new business model revive drug discovery?, Economist, 2 November 2006, where it is referred to the result of a study conducted by CRM International.

\(^{96}\) See answers to CFI’s questions of 21 April 2006 JURM(2006)4052, par. 16-25 and the Commission decision at par. 167-169.
In the *Glaxo* case, such losses represented an irrelevant fraction of the entire budget. Therefore, parallel trade could not have harmed GSK’s incentive to innovate, by forcing it to reduce the percentage of profits to be devolved to research, especially given the fact that R&D is fundamental for the competitiveness of a pharmaceutical company and is the last investment to be reduced in case of financial difficulties.

5. **Conclusions**

This paper has analysed the welfare effects of dual pricing, a two-tier price system that consents to pharmaceutical manufacturers to obstruct parallel trade by rendering economic uninteresting exports to traders.

Given that an optimal pharmaceutical regulation should be able to accomplish and reconcile three overriding policy objectives - equitable access to medicines from consumers, cost containment for health care systems, and improved efficiency of the industry -, the investigation conducted in this paper showed that dual pricing does not look to be the most appropriate tool to achieve such an optimality.

The analysis above, in fact, showed that dual pricing strategy diminishes products availability, by impeding traders to serve a segment of the demand specifically nourished by parallel trade in the importing markets, and does not allow consumers to enjoy savings through cheaper products.

The fact that price are regulated in the pharmaceutical market is not capable of upsetting such assessment, given that this form of governmental intervention does not impede price competition in importing markets. Such a conclusion is further underpinned by the evidence presented in the *Glaxo* case with regards to the measures taken by the health care systems of the importing countries in order for public finances to benefit from the presence of cheaper products in the market.

With regards to the policy goal of improved efficiency, this paper argued first of all that parallel trade could not be the only determinant in the preservation of innovation incentives from pharmaceutical companies. Given the heavy role of regulation, and the length and the uncertainty that characterise the discovery process in the pharmaceutical market, it is impossible to single out such a correlation. Moreover, the paper argued also that, given the high return earned by the pharmaceutical industry globally, it is unlikely that the losses suffered in some European market will subtract the necessary resources to the development of new molecules.