

# Article 82 and Price Discrimination in Patented Pharmaceuticals: the Economics

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## Introduction

The pharmaceutical industry has long been troubled by parallel trade in patented medicines in the EU, since this arbitrage market has substantially reduced the profitability of such products.<sup>1</sup> A solution appeared likely when the EC Advocate General recommended a decision in *Merck v Primecrown* on June 6, 1996 that would have allowed the patent-holder to prevent unauthorised imports of its own products from other parts of the EU; but the recommendation was rejected by the European Court of Justice (ECJ).<sup>2</sup> This judgment turned not on the merits or otherwise of parallel trade, but on the ECJ's view that it was for legislators rather than Courts to find a remedy if indeed one was to be found.

A similar view provided the basis for a recommendation from the Council of Ministers to the European Commission to the effect that the Commission, having a monopoly in the initiation of legislation that might affect more than one EU country, should bring forward proposals to resolve tensions between policies to protect intellectual property, and policies designed to promote free trade within the EU. However, the issues have not yet been effectively addressed by policy makers.

In the courts, cases concerning trade marks and trade dress issues in pharmaceuticals are seen as also relating

to parallel trade, and this has influenced their outcome.<sup>3</sup> Generally, the Commission has sought to discourage restrictions on parallel trade.

Bayer was alleged to have infringed Art.81 for agreeing with its distributors that it would limit supplies of its product Adalat to the volumes likely to be used in each part of the market, and thereby reduce the opportunities for profitable parallel trade. However the Court found that Article 81 did not apply, since it was held that there was no agreement between Bayer and the distributors concerned.<sup>4</sup> The merits or otherwise of limiting the supplies of product likely to be diverted into parallel trade were therefore not addressed.

As a result of the decision in *Bayer*, there is speculation that the Commission is planning to bring cases under Art.82 against pharmaceutical manufacturers that limit supplies without agreement from distributors. There has recently been a reference from Greek Competition Commission to the ECJ of GSK's alleged practice of limiting supplies there when faced with explosive demand, most likely from traders intending to re-export.<sup>5</sup> The Advocate General's opinion favours GSK's policy, concluding that refusal to supply does not automatically constitute an abuse of a dominant position, in the particular circumstances of the European pharmaceutical industry.<sup>6</sup>

The GSK case and other prospective cases under Art.82 may provide the best opportunity thus far for the economics of the issues raised by parallel trade in patented medicines to be properly heard. This is because there is relatively little case law on how the Art.82 concept of "abuse of a dominant position" should be interpreted, and a need for fundamental analysis.<sup>7</sup>

This article outlines the economic issues on which such cases should depend. It argues that although issues of market definition and dominance may be important elements in individual cases, the heart of the issue lies in understanding how the dynamics of competition would be affected by increased scope for price discrimination in a sector that is regulated in detail. The cases should turn on the justification or otherwise of price discrim-

3 *Glaxo Group Limited v Dowelhurst Limited* [1999], HC; Joined Cases C-427/93, 429/93 & 436/93 *Bristol-Myers Squibb v Paranova* [1996]; [1996] E.C.R. I-3457; Case C10/89 *CNL-SUCAL v HAG GF* [1990]; [1990] E.C.R. I-3711.

4 Joined Cases C-2/01 & 3/01 P *Bundesverband der Arzneimittel-Importeure eV and Commission v Bayer AG* [2004].  
5 Greek Competition Commission Decision 229/III/2003, January 22, 2003.

6 Commission Press Release IP/04/87, October 28, 2004; Case No.87/04 *Syfiat v GSK*.

7 Vickers, John, "Abuse of Market Power", Speech to the 31st conference of the European Association for Research in Industrial Economics, Berlin, 2004.

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1 The term "parallel trade" refers to arbitrage in drugs (normally patented products) between different parts of the EU. The arbitrageurs offer a distribution channel parallel to that provided by the manufacturer and its intended normal distributors.

2 Joined Cases C-267/95 & 268/95 *Merck v Primecrown* [1996]; [1996] E.C.R. I-6285.

ination, rather than on effects on parallel trade *per se* or on innovation, important though these effects may be.

## A. Dominant position?

### *Defining the market*

Article 82 prohibits the abuse of a dominant position. Since in competition law a dominant position is identified in relation to a market, market definition is a natural starting point for analysis, requiring the identification of the group of products or services which are close enough substitutes that suppliers of them are competitively constrained, and then identifying the geographical area within which consumers of the defined product/service are willing and able to switch suppliers

In merger cases involving pharmaceutical manufacturers, competition authorities have defined markets by reference to the therapeutic qualities of the products supplied by the parties to the merger.<sup>8</sup> In the merger case, the question being asked is whether there will be a reduction in the competitive constraints on the merged entity as a result of the combination.<sup>9</sup> It is important to take into account the time dimension. Most obviously, if a patent is about to expire, then entry conditions and market shares will change. In cases turning on the effects on the value of patents, it is always important to take into account effects in the markets for innovation, in particular in the discovery and introduction of new drugs, since this is a prime arena for competition in this industry.<sup>10</sup>

In a case in which the alleged abuse is a restriction on supplies of products that might be used for parallel trade, it is worth considering whether the basis for market definition should be different from a merger case. This is because the transactions that are likely to be affected are either in the markets for distribution services or in the process of settling reimbursement prices by

healthcare authorities. The possible bases for market definition would then include:

a) The market for products for the purpose of parallel trade (the arbitrage market). Here the purchasers are traders intending to re-sell the product into another part of the EU—almost certainly, into another country—from that in which it is purchased. In this market, the therapeutic qualities of the products are irrelevant, since there are no obligations on the traders to supply, and all that matters are the price differences between the places of purchase and those of sale.<sup>11</sup> It seems unlikely that any single supplier could have a dominant position in this market (although it is theoretically possible that patent-holders might be in a position of collective dominance).<sup>12</sup>

b) The market for sale of products to a national health service, perhaps through a position on a list of medicines eligible for reimbursement.<sup>13</sup> Health services are increasingly comparing the marginal utility at a given price of alternative medicines; unless a new product offers a competitive result, in expected cost per Quality Adjusted Life Year (QALY) or similar measure of health outcome, it may not be approved for reimbursement. Since the main objective of a purchasing authority is presumably to achieve the best health outcomes from its available budget, there is every reason why such comparisons should *not* be limited to a particular therapeutic class.

Since these alternatives might have the effect of making a firm that had a dominant position in the product market as defined in merger cases not dominant in the Art.82 cases, careful analysis of these issues will be needed. The market definition adopted should always depend on the precise competition issue requiring analysis.

In the remainder of this article, it is therefore assumed that the decision has been made on market definition, and that the court will then proceed to the next stage.

8 Morse, M. Howard, "Product Market Definition in the Pharmaceutical Industry" [2003] *Antitrust Law Journal*, December.

9 A similar approach to market definition will probably also be followed in another type of case under Art.82 (or equivalent legislation in the USA) in which it is alleged that there has been an abuse of administrative procedures in order improperly to extend intellectual property rights (C-223/01 *AstraZeneca A/S v Lagemiddlestyrelsen* [2003]; Federal Trade Commission, *Bristol-Myers Squibb case* [2003], File Nos 001 0221, 011 0046, and 021 018, Docket No.C-4076, March 7).

10 "The Development of Analytical Tools for Assessing Market Dynamics in The Knowledge Based Economy" [2003] *Europe Economics*.

11 Jenny, Frederic, "Pharmaceuticals, Competition and Free Movement of Goods", EU Competition Law & Policy Athens Conference Paper, April 19, 2002.

12 "Study On Assessment Criteria for Distinguishing Between Competitive and Dominant Oligopolies in Merger Control" [2001] *Europe Economics*.

13 In many European countries, national health services are funded by multiple health insurers. However, decisions about what medicines to reimburse, and at what prices, are usually taken on a national basis. Hence, such multiple insurers can be regarded as a single purchasing entity for market definition purposes.

### Assessing dominance

Once a market has been defined, for Art.82 the question is whether or not a particular company has a dominant position. Current and forecast market shares are the starting point, but other factors are also relevant. In pharmaceuticals, important issues concern customers' purchasing power, regulation, price control and entry conditions.

In most purchases by health services, there is strong purchasing power, sometimes virtually monopsony power within a defined geographical area. There may be regulations preventing a supplier from increasing its prices; and in some countries there are price controls at the time a product is launched. Entry is strictly controlled by a system of marketing authorisations. Moreover, it is often practically impossible for a manufacturer whose products are important medical supplies to withdraw from a market once it has entered; such exit barriers are also significant.

Do such facts mean that individual patent-holders are not in a dominant position? Dominance may be understood to mean an ability to alter prices without fear of effective reprisal from customers or competitors; and these are the circumstances in which even a pharmaceutical company with exclusive control of an important patented product is unlikely to find itself.<sup>14</sup> However, the underlying economic reason why in general a purchaser with a monopsonistic position has countervailing power, and is able to prevent a supplier with a high market share from exercising dominance is that the purchaser would be able to walk away from the deal. This may not be possible in the case of an important patented product. Thus the correct way of understanding the situation is likely to be that *both* the supplier and the customer have dominant positions—a monopsonist facing a monopolist.

In this type of situation, which is not particularly uncommon, there is in theory a wide range of possible outcomes to negotiations, although in practice deals tend to be done in a way that leaves a clear margin of advantage to both parties.<sup>15</sup>

14 The ECJ has defined a dominant position as "a position of economics strength enjoyed by an undertaking which enables it to hinder the maintenance of effective competition on the relevant market by allowing it to behave to an appreciable extent independently of its competitors and customers and ultimately of consumers." Case C-322/81 *NV Nederlandsche Banden Industrie Michelin* [1983] at [30]; Case 27/76 *United Brands v Commission* [1978] at [65]; [1978] E.C.R. 207.

15 Nash, John, "The Bargaining Problem" (1950) 18 *Econometrica*, pp.155–162. Rubinstein, Ariel, "Perfect Equilibrium in a Bargaining Model" (1982) 50 *Econometrica*, pp.57–109.

Although the regulatory framework and the nature of the purchasing power are thus fundamental to understanding the likely effects of particular interventions, they do not in themselves mean that Art.82 cases could not be successfully brought against the patent holders.<sup>16</sup>

### Alleged abuse

#### *The practices that might be adopted*

It follows from what has been said above that although there are arguments to be had about whether in particular cases the manufacturer has a dominant position, our main attention should be addressed to what should count as an abuse of such a position. Should it count as an abuse if research-based pharmaceutical manufacturers take steps that would in one way or another limit the supplies of patented products to what local patients are likely to need, with the result that different prices can be charged to different customers while arbitrage is inhibited or prevented?

It is useful at this stage to indicate different types of measures that a manufacturer might adopt. These include:

- a) Vertically integrating with distributor(s), either by acquisition or by contract (so that the distributors became the agents of the manufacturer rather than its customers).
- b) Refusing to supply any customer thought to have engaged in parallel trade.
- c) Imposing a condition of sale that prohibits re-sale other than to specified types of customer.<sup>17</sup>
- d) Limiting supplies to an estimate of local market needs. If the distributor then sold the supplies into parallel trade markets, the supplier rather than the manufacturer would be responsible for the resulting local shortages.
- e) Selling at a single price throughout the EU, but offering rebates to hospitals and other parts of the health service according to proof of the amounts used for local patients.

16 In the *Napp* case in the UK, the Office of Fair Trading found that the fact Napp was subject to the PPRS and sold only to the NHS did not mean it might not have abused its market power in dealings with the NHS (Office of Fair Trading (2001), Decision No.CA98/2/2001, March 30).

17 If such a condition were adopted by agreement between the supplier and the distributor rather than being imposed by the supplier as a condition of sale, it would be relevant to Art.81 rather than Art.82.

All of these options would allow the manufacturer to introduce different prices in different countries or to different classes of customer, according to its assessment of the most profitable price and volume of supplies in each market. This is because any of them has the potential to prevent arbitrage, which is a necessary condition for sustainable price differentiation. These options also have in common that they would make possible more efficient distribution systems than those in place at present, since they would reduce the duplicated shipments inherent in parallel trade.

There are of course also important differences between these potential practices, and for the purpose of the present discussion the last item in the list, selling at a single EU price with subsequent rebates according to proven use, probably best encapsulates the central issues.

### *The abuses that might be alleged*

The most important results of any of the potential practices outlined above that might be alleged to be abuses are:

- a) Taking advantage of a dominant position at the manufacturer/supplier level to lessen competition in the market for distribution services.
- b) Lessening competition in a product market in an importing country by preventing parallel traders from offering the same goods at lower prices.<sup>18</sup>

The sorts of practice outlined would almost certainly have these effects; the question is whether they should be regarded as an abuse.<sup>19</sup> This is a legal term, not one that has been derived from the economics literature. To the economist, for conduct to be an abuse it must be conduct that would only be possible for a firm with market power (and not merely transitory market power) and have the purpose or effect of restricting competition from efficient firms already in the market or from efficient potential entrants (which may be summed up as exclusionary conduct which damages the competitive process), or, more arguably, conduct that exploits the absence of effective competitive constraints by shifting welfare from consumers to producers. Either form of

18 To some commentators, anything that limits trade within the EU is offensive, but such limits do not constitute an abuse *per se*.

19 There is an ongoing review by the EC of Art.82 that will presumably consider issues of this sort in great depth. This will doubtless then influence the decisions of the national competition authorities in applying the Article (for example, since May 1, 2004 it is the OFT that will enforce Art.82 in cases affecting parallel trade into the UK).

abusive conduct will be damaging to consumers in the short or long term. The question is whether the practices under consideration here would be likely to improve or damage the competitive process and hence on balance be in the interests of those affected, particularly patients.

### *Economic analysis of the alleged abuse*

Economic analysis should therefore address the following empirical questions, among others:

- Will the practice facilitate price discrimination; and if so is this beneficial?
- Will the practices increase the value of patents and if so is this likely to lead to a significant improvement to incentives for the development of new medicines?
- Will the elimination of parallel trade improve or harm the efficiency and competitiveness of the distribution system?

### *Price discrimination*

#### *a) Price discrimination in theory and practice*

Concerning price discrimination, the starting point is that wherever a producer has incurred fixed costs that are substantial in relation to the marginal costs of production and distribution, it will have to charge more than the marginal costs if it is to continue in business. If the market is willing to pay enough to remunerate the fixed costs, it is efficient that this should happen.

Where the ability or willingness to pay of different groups of customers varies significantly, there may be groups that would wish to be customers at prices that would cover the marginal costs, but not at the average cost. This means that if—for whatever reason—all customers have to be charged the same price, there would be potential efficient trades that could not take place. In these circumstances, permitting price discrimination would allow increased output and improve economic efficiency.

These ideas are not new. It is well understood, thanks to Ramsey and Boiteux, that the most efficient way to cover some fixed cost of production is to implicitly tax those markets that will be least affected by higher prices, *i.e.* those with a lower elasticity of demand.<sup>20</sup>

On the same logic, the EC regulatory guidelines for railways require that:

The level of charges must not, however, exclude the use of infrastructure by market segments which can pay at least

20 Glynn, Dermot, "Economic Aspects of the Single European Market in Pharmaceuticals" [1999] E.C.L.R. .

the cost that is directly incurred as a result of operating the railway service, plus a rate of return which the market can bear.<sup>21</sup>

Libraries, museums, galleries and conference organisers all systematically discriminate in favour of students, old age pensioners, and other groups thought either to be particularly deserving or particularly unlikely to be customers at the average price needed to cover all costs.

Software companies charge different prices for their licences according to the number of users, although this makes no difference to their costs.

There are many such examples, generally without objections from the competition authorities.

There are, however, arguments against allowing a monopolist to practice price discrimination. These rely on the view that such discrimination would be unfair or unreasonable in one of two senses:

- It may be argued that although the sum of producer and consumer surplus will be increased, price discrimination would allow the monopolist to increase its profit while the aggregate consumer surplus might be diminished. Whether competition policy should aim at maximising total welfare rather than consumer surplus is a debated issue. However, it is important to notice that public policy has established intellectual property rights specifically in order to allow the possibility of surpluses for those patent holders whose innovations have proved to be beneficial.
- Secondly, discrimination may be held to be unfair where it is applied to customers within the same class. The questions of equity between consumers bring in more than purely economic considerations. However, there would surely be wide support for the view that it is fair to apply differentiated mark-ups for patented medicines according to ability to pay.<sup>22</sup>

Thus the most efficient and fairest way for patent-holders to recover the surplus over production costs to which their patent entitles them is to charge different prices in different parts of the world market according to ability and willingness to pay.

<sup>21</sup> European Council Directive 2001/14, which sets out various responsibilities of Member States relating to railway transport.

<sup>22</sup> To illustrate the importance of this: the GDP per head of the new accession countries is on average about 25 per cent of that in the countries to which parallel imports are typically sent, such as the UK, Denmark, Germany ("G 10: Recommendation XIV the economic case" [2002] *Europe Economics*, Table 2.1).

Because of the high sunk costs of the research and development that precede patent applications, and the relatively low costs of manufacturing and distributing the products once approved, discriminatory pricing has the potential to increase production and use of the patented product to the benefit of patients and manufacturers alike.

However, such pricing will only be possible if the prices charged in low-income parts of the market do not lead to arbitrage that will undermine the higher prices that customers elsewhere are willing to pay.<sup>23</sup>

In the case of pharmaceuticals, there is evidence that parallel trade in the EU market has in practice contributed to a reduction in the extent of price discrimination between different national markets within the EU.

A study of pharmaceutical prices in different EU countries over the period from 1986 to 2001 is summarised below.<sup>24</sup>

**Chart 1: Standard Deviation of Pharmaceutical Prices in Selected EU Member States (1986 - 2001)**

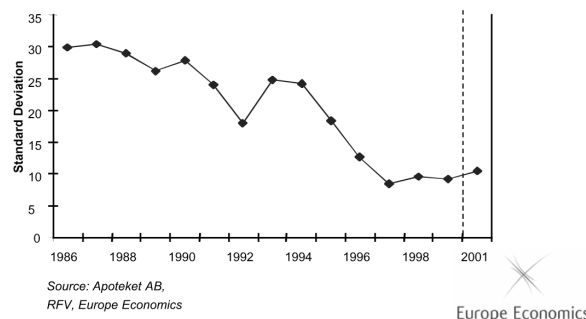


Chart 1 shows the standard deviation of the prices of selected drugs in selected EU countries; a conventional measure of the extent of divergence. The fall in the standard deviation between the mid-1980s and about 1997 is striking. In other words, over this period, as one would expect, prices were converging significantly.<sup>25</sup>

This appears to confirm that under present policies,

<sup>23</sup> This (obvious enough) point explains why, in a related context, the EC has recently taken active positive steps to encourage pharmaceutical companies to charge differentiated (lower) prices in developing countries. The new rule states that if prices are lower than a defined level, then the EC will exert its full influence to prevent parallel trade into the EU from the parts of the world to which the low-price sales were made (Council Regulation 953/2003).

<sup>24</sup> "G 10: Recommendation XIV the economic case" [2002] *Europe Economics*.

<sup>25</sup> The convergence halted in about 1997, perhaps reflecting government interventions and new regulations in the low price countries. Two countries which often had the lowest internal prices for medicines were Greece and Spain (sometimes Italy and occasionally Austria, Denmark, Portugal and Sweden). Actions on prices in those source countries for parallel trade included:

Table 1: Present Position (Base Case)

Rich country (importer)				
	Volume supplied	Sales revenue of manufacturer (£)	Expenditure by final purchaser (£)	Gross profit of // trader (£)
Direct sales	50	50	50	
From // importer	50	(sales made in poor country)	40	15
<b>Total</b>	<b>100</b>	<b>75</b>	<b>90</b>	<b>15</b>
Poor country (exporter)				
	Volume supplied	Sales revenue of manufacturer (£)	Expenditure by final purchaser (£)	Gross profit of // trader (£)
Direct sales	50	25	25	
To // exporter	50	(on product that will be used in the rich country)	0	
<b>Total</b>	<b>100</b>	<b>50</b>	<b>25</b>	<b>15</b>
<b>Total from both countries</b>	<b>150</b>	<b>100</b>	<b>115</b>	<b>15</b>

that facilitate arbitrage, the extent of price discrimination in the EU market for pharmaceuticals has tended to reduce.

*b) Would increased price discrimination be in the interests of consumers?*

The tendency to convergence and away from price discrimination that characterises the EU market for pharmaceuticals will clearly be stronger if arbitrage such as parallel trade is allowed to continue than if it is prevented. The question then arises whether such convergence might not mean lower average price levels, so that customers as a whole would benefit at least in the

short term. There are however several reasons for expecting that measures that facilitate price discrimination will be beneficial, in terms of wider access to medicines and more rapid introduction of medicines across various EU States, and in terms of prices.

The size and profitability of each national market will be an important consideration for the company seeking to increase its profits through discrimination. For example, it would be rational for a company to launch a new product in the major markets in which higher prices can be expected, and then to try to negotiate prices in other markets. It is well known that the launch dates of new products have indeed lagged in lower-income Member

— *Greece*. In October 1997 a decree was implemented which fixed pharmaceutical prices by reference to the lowest prices charged in Europe. In March 1998, the drachma was devalued on entry into the EMS by 13.8%, without adjusting internal pharmaceutical prices.

— *Spain*. In August 1996, voluntary price freeze extended to July 1998. January 1998, prolongation of price freeze until December 1999. September 1999, decree imposing an average price reduction of 6%. June 2001, 15% price reduction for certain medicines.

States.<sup>26</sup> It would be possible to model the launch strategies that would be most profitable, taking account of size and price as well as other factors specific to each product.

Measures to facilitate price discrimination might also be beneficial to consumers in both rich and poor countries in terms of average prices of products. In order to clarify and illustrate this point, which some readers might perhaps find counter-intuitive, we consider a “rich country” and a “poor country”, each with a population that would benefit from 100 units of an important patented medicine. The patent-holder sells 50 units in the rich country, at £1 per unit, and 100 in the poor country, at half that price. The arbitrageur (parallel trader) buys 50 at the lower price and sells at slightly less than the manufacturer in the high price country, at say £0.80. Thus patients in the rich country receive the 100 units indicated as medically desirable, half of which come through parallel trade. Patients in the poor country receive only 50 units.

Table 1 shows this, representing a base case with which the likely results of the measures being considered can be compared.

The patent holder receives £1 per unit on the 50 direct sales in the rich country and £0.50 on the 100 sales in the poor country (half of which are to be re-exported), making £100 in total. The parallel trader pays £25 for the 50 units, and sells at £40, earning a gross margin of £15.

Thus for 100 units of its product used in the rich country the patent holder receives £75, and the purchaser in the rich country pays £90.

Table 2 shows the initial result of the measure being considered, before any adjustments to prices or other competitive response; this simply removes the parallel trader from the picture.

**Table 2: With the Measure: Before Competitive Response**

Rich country			
	Volume supplied	Sales revenue of manufacturer (£)	Expenditure by final purchaser (£)
Direct sales	100	100	100
From//importer	0	0	0
<b>Total</b>	<b>100</b>	<b>100</b>	<b>100</b>

<sup>26</sup> “Access to important new medicines” [1998] *Europe Economics*.

Poor country			
	Volume supplied	Sales revenue of manufacturer (£)	Expenditure by final purchaser (£)
Direct sales	50	25	25
To//exporter	0	0	0
<b>Total</b>	<b>50</b>	<b>25</b>	<b>25</b>
<b>TOTAL from both countries</b>	<b>150</b>	<b>125</b>	<b>125</b>

The patent holder’s profits are increased by £25, and the expenditure of the purchasers in the rich country is increased by £10.

However, it would be completely unrealistic not to expect a competitive response to the new situation.

In the first place, the negotiations between the patent holders and health service purchasers in the importing country would take on a new dynamic. There would be no threat of parallel imports, so within whatever scope it has under the regulatory regime the patent holder might try for a higher price: this is one of the possible forms of abuse noted above. On the other hand, the purchaser is likely to be to be a government or quasi-government insurance fund, with power to deny most or all sales in the country in question. It might seek a share of the savings from the removal of the parallel traders’ £15 gross profits, reasoning that the manufacturer should be content with anything above £75 for the 100 units. The outcome of such negotiations, between suppliers with monopoly power and purchasers with monopsony power, is inherently uncertain; but as we have already observed, they may tend to settle at an outcome with benefits to both parties.

The outcome of negotiations in the poorer country can be predicted with more confidence. It can be assumed that the purchasers would wish to take a larger volume if the price could be sufficiently reduced (price net of discounts, if the practice has taken the form of a single EU list price with negotiated discounts according to local use). The reserve position of the patent holder in such negotiations has been transformed; it will now have an incentive to maximise its margins above production and distribution cost in the country concerned. It knows that the purchaser was willing to pay £25 for 50 units; if the manufacturing cost were about £0.05 per unit, the manufacturer would be in pocket if it supplied 100 units for local use for anything more than £27.50. The purchasing

healthcare service will not want to increase total spending by much, but would be interested in being able to increase the available supplies at reduced prices.

Table 3 assumes for the purpose of illustration that the price in the poor country is reduced from £0.50 to £0.30 per unit, and that sales increase to 100 (the assumed ideal level in medical terms). In the rich country, it is assumed that the health service purchaser takes some of the money that would previously have gone to the parallel traders, but leaves some advantage also to the patent holder.

**Table 3: With the Measure: After Price and Volume Adjustments**

Rich country			
	Volume supplied	Sales revenue of manufacturer (£)	Expenditure by final purchaser (£)
Direct sales	100	85	85
From//importer	0	0	0
<b>Total</b>	<b>100</b>	<b>85</b>	<b>85</b>
Poor country			
	Volume supplied	Sales revenue of manufacturer (£)	Expenditure by final purchaser (£)
Direct sales	100	30	30
To//exporter	0	0	0
<b>Total</b>	<b>100</b>	<b>30</b>	<b>30</b>
<b>TOTAL from both countries</b>	<b>200</b>	<b>115</b>	<b>115</b>
(Comparison with base case)	+ 50	+ 15	No change.)

On the assumptions illustrated, the result of allowing the measure should be a significant increase in production and the proportion of patients able to benefit from the treatment, a significant increase in the patent holder's profit; no change in total expenditure; and a significant reduction in the average price.

If economic research applied to a particular Art.82 case showed that the results illustrated above are indicative of what would be likely to happen in practice, the writer would argue that the practice that led to them should not be regarded as an abuse.

*The value of patents*

All the arguments discussed here are focused on patented medicines: products whose patents have expired are in a different economic category.

Price discrimination as described above will increase the value of patents and thus increase the incentives for future development of new medicines. Parallel trade is concentrated on the most successful patented products that contribute a major part of the industry profitability.<sup>27</sup> The result of a practice that would prevent parallel trade in the EU would increase the return to patent holders, and the orders of magnitude involved would be significant, even in the context of a global industry most of whose revenues are earned in the USA.<sup>28</sup> It follows that there would be an improvement in the prospects for future innovation, and in the keenness with which the competitive research process is pursued.

It should not be necessary to attempt a precise quantification of such an effect, even if such quantification were possible (which is unlikely), since the direction of the effect is unambiguous.

*The distribution system*

It is not necessary to spend much space considering whether the result of the type of practice we are considering would be to improve the distribution system. It is inherently wasteful for products to be exported, then re-imported; or for products to go to Denmark from Ireland via Greece. The patent holders should find it a straightforward matter to show such an advantage compared to the present arrangements.

It is worth noting here that the reason why the FDA does not wish to permit parallel trade into the USA is that it would increase the risk of counterfeit or otherwise unsafe product being used.

Moreover, as experience in Greece and elsewhere has illustrated, security of supplies can also be threatened by

27 According to recently published research by the LSE (Kavanos, P., Costa-i-Font, J., Merkur, S., and Gemmill, M., "The Economics Impact of Pharmaceutical Parallel Trade in European Union Member States: a Stakeholder Analysis" (2004) LSE Health and Social Care special research paper, LSE), the cost savings from parallel trade purchases (for the countries and products studied) amounted to about 14% of total sales, at pharmacy purchasing prices. Of those savings, between 6 and 13% accrued to health insurers while between 85 and 93% accrued to the parallel traders. Nothing significant accrued to either consumers or pharmacies. Since the savings were made at the expense of the original manufacturers, that represents a large profit transfer from research-based business to traders who do no research, to the detriment of innovation (para.6.7 and Table 6.14).

28 Kavanos, P., Costa-i-Font, J., Merkur, S., and Gemmill, M., "The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: a Stakeholder Analysis" (2004) LSE Health and Social Care special research paper, LSE.

parallel trade, if product intended for the local market is diverted into export markets.

## Conclusion

This article has argued that the question of price discrimination is at the heart of the analysis that will be necessary for the satisfactory resolution of cases brought under Art.82 against any pharmaceutical patent holder that adopts measures such as rebates from a single EU price for patented medicines, according to local use. Although price discrimination is included in the examples in Art.82 of abusive conduct, it is not (and nor should it be) a *per se* prohibition even if it is conduct of a dominant firm. There has to be the equivalent of a rule of reason approach and that ought to take account of the types of effect reviewed in this article, everything of course depending on the facts of the particular case.

We would, however, expect that, as a result of measures such as those discussed here, prices would be lower if the practice was allowed than they would otherwise be in some (low income) parts of the EU; the outcome in some high income parts will depend on the outcome of negotiations between powerful buyers and powerful suppliers, but prices would be lower on average, and production would be higher. The value of patents would be higher so that the incentives for R&D would be increased. The efficiency of distribution systems should be significantly improved.

While each case must depend on its own facts, these considerations point to the conclusion that in the case of patented drugs the competitive process is likely to operate more effectively in the interests of consumers, in both the short and long term, with practices that facilitate price discrimination by restricting arbitrage. It then follows that such practices should generally not be regarded as an abuse even if engaged in by a company that is held to be in a dominant position.