Parallel trade in pharmaceutical products following the ECJ's *Bayer* judgment: Can a case be made under Article 82 EC treaty?

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The background

In January of this year, the European Court of Justice ('ECJ') delivered the final verdict in the Adalat saga.[2] At issue was whether arrangements to limit parallel trade within the EU, devised and implemented unilaterally, could be prohibited as anti-competitive agreements under Article 81 EC Treaty.

Differences in, primarily, national regimes governing the pricing of pharmaceuticals and healthcare spending, have led to substantial price differences between Member States.[3] This has in turn created a significant, and growing, parallel trade activity. Wholesalers purchase in low-priced countries to sell at higher prices in the country of importation, effectively free-riding on the price differentials. Pharmaceutical manufacturers, in order to manage their inventory and production capacity, have unilaterally refused to sell, or have reduced quantities made available to wholesalers. In some cases, these measures have been implemented in order to restrict parallel imports; in others they are alleged to have the effect of restricting parallel imports.

Action taken to restrict parallel trade is potentially in breach of EC competition law, either as a restrictive agreement (Article 81 EC Treaty), or as an abuse of a dominant position (Article 82 EC Treaty). Since Bayer was not dominant with respect to its Adalat product, the question before the court was whether its attempts to restrict parallel trade could be properly qualified as a restrictive 'agreement' under Article 81.

The ECJ, confirming the judgment of the Court of First Instance ('CFI'), found there to be no agreement between Bayer and its wholesalers on the facts of the case. Without an agreement, and without a finding of dominance, the matter was beyond the scope of EU competition law, even though Bayer's unilateral actions were intended to restrict parallel trade of its Adalat product.

Following the *Bayer* judgment, a pharmaceutical manufacturer can, unilaterally and without a dominant position, implement certain measures to limit parallel trade without infringing EU competition law. Several manufacturers in recent years have set up so-called 'supply quota systems', in some cases unilaterally restricting their supplies to wholesalers to what each wholesaler requires for its domestic supplies, plus a limited margin.[4] There have also been outright refusals to supply existing or new customers.

What, however, is the position if unilateral restriction of parallel trade[5] is carried out by a dominant undertaking? Would this be an infringement of Article 82 EC Treaty (prohibiting the abuse of a dominant position)? The matter is the subject of hot debate in industry and regulatory circles. It is also the subject of a pending preliminary reference before the ECJ from Greece.[6]

Restrictions of parallel trade tend to be particularly controversial because they are in direct conflict with the fundamental aim of market integration that is enshrined in the EC Treaty, an aim which is also pursued by the Treaty's competition rules.

Attempts to harmonise national pricing and reimbursement regimes by law have so far failed. The view often expressed in the past was that harmonisation of prices might nevertheless come about through parallel trade. Yet there is no evidence from any industry sector that parallel trade has led to a real approximation of prices in the EU. Industry players and the European Commission ('Commission')[7] are in agreement that, on the facts, such harmonisation is even less likely in the pharmaceutical sector since most of the financial benefit accrues to the parallel trader, with little or no impact on prices to the consumer.

It is not the case, therefore, that restrictions of parallel trade defeat the integration of pharmaceutical markets. That being the case, defending parallel trade on the basis that it will help achieve market integration through price harmonisation is misguided.

This article analyses to what extent a case could be made under Article 82 EC Treaty[8] to prohibit unilateral restrictions of parallel trade, addressing separately the issues of market definition, dominance and abuse.

Defining the relevant product and geographic market

Dominance, or market power, derives from a number of factors, none of which, taken separately, is necessarily determinative.[9] Although the European Commission will typically start with an evaluation of market share when assessing dominance, the significance of market share will vary depending on the structure of the market concerned. Case law confirms that high market shares do not in themselves justify the assumption of a dominant position.[10]

Therefore, whilst the analysis of the relevant product and geographic market is a necessary step in determining market share, its importance in the overall exercise of determining dominance will depend on the facts and circumstances of the case at hand.[11]

There is virtually no EU case law on market definition in the pharmaceutical sector outside the field of merger control. There have been a handful of Article 81 EC Treaty cases[12], where market definition plays a limited role in the overall assessment, and no Article 82 EC Treaty cases as yet.[13]

The main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings concerned face.[14] Hence, different market definitions are conceivable, depending on the level at which the undertakings concerned face competitive constraints. That level will be determined by the nature of the alleged restriction, or the change in the structure of competition, under scrutiny. For example, the market analysis for a merger between two pharmaceutical wholesalers will be different from that relating to a merger between two pharmaceutical manufacturers.[15] Similarly, an Article 82 analysis will not necessarily follow merger control precedents.

From an economic point of view, demand substitution consti-

tutes the most immediate and effective disciplinary force over suppliers of a given product. As a first step, therefore, the Commission will analyse which products are regarded as substitutable by the consumer by reason of the products' characteristics, prices and intended use.[16]

In pharmaceutical merger cases, the Commission has used the Anatomical Therapeutic Chemical classification system ('ATC') as a starting point for its market definition analysis.[17] The ATC categorises medicinal products into different groups according to the organ or system on which they act, and their chemical, pharmacological and therapeutic properties. In particular, the ATC third level[18] groups medicines in terms of therapeutic indications and pharmacological properties—in other words, their intended use and characteristics—and hence provides a useful basis for the Commission's market definition analysis. The Commission will, however, often refine the ATC third-level categories in order to arrive at a market definition that it considers better reflects the substitutability between different products. This can be because other criteria[19] cause it to group products with similar therapeutic use into different markets, or because the ATC third level does not properly reflect therapeutic use.[20]

The relevant geographic market in merger cases has so far been defined as being national in scope, justified mainly by the existence of national marketing authorisation, pricing and reimbursement systems, and differences in prescribing habits along national lines.

As already mentioned, there are as yet no EU precedents on defining the relevant market for the purpose of assessing a refusal to supply parallel traders. At which level of competitive constraints should the assessment be conducted? Is it at the level of the parallel trader, who sees his supplies for a given product reduced or refused? Or is it at the retail level in the country of importation, where intra-brand competition is being hampered as a result of reduced parallel imports?

Let's consider first the level of the parallel trader. Starting from the main criterion of demand-side substitutability, what products do parallel traders consider to be substitutable?

The issue has been addressed by Frédéric Jenny, a leading national antitrust official and commentator, in a paper presented to the Hellenic Competition Authority's EU Competition Law and Policy Conference in April 2002.[21] He argues that parallel traders "export drugs for which there is the largest margin between the wholesale price in the country of export and in the country of import" and that, hence, if "two drugs have the same potential profit margin, it is possible that they can be considered to be substitutes by parallel exporters". In other words, the relevant market would include all pharmaceutical products that are capable of being profitably (taking account of both volume and margin) traded from one Member State to another. This would capture a range of products across the European Union in what is effectively an arbitrage activity developed on the back of national pricing and reimbursement systems.

Following Jenny's theory, the geographic scope of the market would presumably comprise all those countries in which the parallel traders can buy products cheaply in order to sell them in another Member State where prices are higher. This would imply that the relevant market should be EU-wide.

Turning to the retail level, here the definition of the relevant product market should be broadly similar to the analysis conducted in merger cases—that is, starting from the product's characteristics, price and intended use. The ATC-3 category seems a reasonable first step to conduct this exercise. In line with the reasoning in merger control cases, the relevant geographic market would, in our view, be the country of importation.

Establishing dominance

Dominance is defined in EU case law as "a position of economic 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".[22] In economic terms, dominance, or market power, refers primarily to the ability of the dominant firm to raise prices above a competitive level for a substantial volume of sales and over a sustained period of time.

Starting with the first of the above potential market definitions, it appears unlikely that a manufacturer would have a significant share of a market comprising all pharmaceutical products that are capable of being profitably traded from one EU country to another. The parallel traders' own confirmation that their business is not curtailed by refusals to supply[23], suggests indeed that these manufacturers do not have the economic strength "to hinder the maintenance of effective competition" at the level of the parallel trader. It would be difficult, therefore, to establish dominance if the relevant market were defined at this level.

The other market, on which competition could conceivably be hindered, is that of the relevant parallel traded product in the country of importation. The manufacturer's policy to restrict parallel trade could, in a worst case scenario, have the effect of eliminating all intra-brand competition in the country of importation with respect to the product concerned. Assuming that the manufacturer has a very high market share, can it be concluded from this that he has sufficient market power to be considered dominant?

Market definition and market power should not be assessed in isolation. Rather, they are tools with which to analyse whether a particular behaviour has anti-competitive effects to the detriment of consumers. The relevant question, therefore, is whether the undertaking concerned has the power to maintain price above the level that would prevail in the absence of the alleged anti-competitive conduct.[24]

Two factors in particular suggest that, in the present case, the pharmaceutical manufacturer does not have the power to maintain prices above the level that would prevail in the absence of the parallel trade restriction.

Firstly, evidence suggests that neither the national health authority nor the patient is being deprived of appreciably cheaper medicines as a result of restrictions on parallel trade.[25] Rather, the manufacturer's aim is to keep for itself the profit that is its due under local pricing and reimbursement regimes and that would otherwise mainly benefit the parallel trader. In other words, parallel imports do not introduce any significant element of (intra-brand) price competition to benefit the consumer. Secondly, the presence or otherwise of parallel-traded products has little effect on the manufacturer's pricing decisions in the country of importation. These decisions are controlled, directly or indirectly, by the pricing and reimbursement regimes in the country of importation, in two respects. At the launch of a product, its price will be subject to control, directly or indirectly, through intervention by the national health authorities. Thereafter, the product concerned is likely to become subject to downward pressure.

These aspects of the market structure suggest that it would be equally difficult to reach a conclusion of dominance on a more narrowly defined market, when assessing parallel trade restrictions.

Proving abuse

The above illustrates the practical difficulties of defining the relevant market and analysing dominance in Article 82 cases, in general, and in the pharmaceutical sector, in particular. Some commentators have suggested that, given these difficulties, less emphasis should be placed on the assessment of dominance and more on the assessment of abuse.[26]

EU case law defines the concept of abuse as "an objective concept referring to the conduct of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is already weakened and which, through recourse to methods different from those governing normal competition, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition".[27] In economic terms, abuse has been defined as a dominant firm adopting a particular mode of behaviour (eg raising prices and/or lowering quality or reducing competition by excluding a competitor) that significantly reduces consumer welfare relative to the alternative of the firm not adopting that mode of behaviour.[28] This definition is consistent with recent policy statements by DG Comp officials.

By way of a preliminary remark, we submit that unilateral action aimed at restricting parallel trade, and hence hindering free movement of goods between Member States, is not in itself an infringement of Article 82 EC Treaty. In other words, there is no per se infringement of competition rules on account of the fact that the goals of the single market may possibly be interfered with.[29] Rather, it needs to be established whether the alleged infringing behaviour, in objective terms, is such as to hinder competition to an appreciable degree by having recourse to methods "different from those governing normal competition".

Freedom of contract is a fundamental principle firmly enshrined in the laws of the EU, as well as those of the Member States. EU competition law does not impose a general duty to deal on dominant undertakings, irrespective of whether a refusal relates to existing or new customers. The CFI explicitly confirmed this with respect to the pharmaceutical sector in the *Bayer* case, where it recalled that the case law of the ECJ "indirectly recognises the importance of safeguarding free enterprise when applying the competition rules of the Treaty where it expressly acknowledges that even an undertaking in a dominant position may, in certain cases, refuse to sell or change its supply or delivery policy without falling under the prohibition laid down in Article 86 [now Article 82]".[30]

Existing case law on refusal to supply confirms that any interference with a dominant undertaking's freedom of contract should be strictly limited and reserved for cases where the supply is indispensable for the downstream activities of the affected customer, in the sense that it risks being eliminated from the market without access to the products concerned. An example would be where the customer deals only or mainly in the dominant firm's products and does not have access to alternative sources or substitute goods.[31]

Empirical evidence suggests that the activities of parallel traders are not being curtailed, let alone being eliminated, as a result of a refusal to supply by pharmaceutical manufacturers.[32] As explained above, the absence of parallel trade does not have any appreciable impact on price competition. Nor should there be any restriction of competition due to reduced availability of supplies in the importing country, since manufacturers and/or wholesalers are obliged to provide sufficient quantities under their public service obligations.

In these circumstances, having regard also to the high burden of proof in cases involving freedom of contract, it is difficult to see how a convincing case could be made out showing appreciable restriction of competition and hence abusive behaviour, irrespective of the market definition adopted.

Conclusion

The restriction of parallel trade in pharmaceutical products does not hinder market integration in the EU. Legal precedent and market structure suggest that it may be difficult to make a convincing case under Article 82 EC Treaty. Moreover, it is unlikely that, on the facts, a restriction of parallel trade by a dominant undertaking would hinder competition in the country of importation to any appreciable degree. As such, one wonders to what extent the Commission would (or should) be eager to commit its scarce resources to an Article 82 case on restriction of parallel trade.

Notes

1 The author wishes to thank Dr A Jorge Padilla, managing director of the LECG European Competition Policy Practice, for his helpful comments on an earlier version of this article.

2 Joined cases C-2/01 p and C-3/07P, *Bundesverband der Arzneimittel Importeure and Commission v Bayer AG*, judgment of 6 January 2004.

3 Price differentials may be as high as 70 per cent in some instances.

4 A number of these cases are currently pending before the Commission, following notification by the manufacturers concerned.

5 Such restrictions may include outright refusal to supply, refusal to supply the full quantity ordered, as well as reduction in the quantities historically supplied. They may be targeted at existing as well as new customers. For ease of reference, in the following text, we refer to all of these restrictions as "refusal to supply".

6 Case C-53/03, *SIFAIT and Others v GlaxoWellcome*, OJ C 101, 26.04.2003. The questions raised by the Greek Competition Authority relate solely to the aspect of abuse.

7 See the Commission's Communication on the Single Market in Pharmaceuticals, COM (1998) 588 where it states that "parallel trade creates inefficiencies because most, if not all, of the financial benefit accrues to the parallel trader rather than to the health care system or patient".

8 The analysis focuses solely on EU law, although the same principles should apply a fortiori as a matter of national competition law in the absence of any restrictive effect in the country concerned.

9 Case 27/76, *United Brands v Commission*, 1978 ECR I-207, para 66, 67.

10 Case No 32.279, *BBI/Boosey & Hawkes*, Commission decision of 29 July 1987, para 18.

11 See Simon Bishop and Mike Walker, *The Economics of EC Competition Law*, Sweet & Maxwell, Second Edition (2002): "(…) it is important that the assessment of dominance does not rely solely on market shares. What matters is the effect on the market of the exercise of this power and this is an empirical question."

12 Joined Cases C-2/01P and C-3/01P, *Bayer*, op cit; Case No 36.957, *GlaxoWellcome*, Commission decision of 8 May 2001.

13 The first Article 82 case is currently pending before the Commission, relating to alleged infringements by AstraZeneca with regard to market entry by generics.

14 See the Commission's Notice on the definition of the relevant market, OJ C 372, 09.12.1997, para 2.

15 See, for example, Case M.2573 *A&C/Grossfarma* where the Commission distinguished between (i) full-line wholesaling; (ii) direct-line, ie direct distribution of products by manufacturers to pharmacists; and (iii) short-line distributors, including parallel importers, who generally focus on a limited range of products.

16 See the Commission's Notice on the definition of the relevant market, para 36.

17 Both the World Health Organisation ('WHO') and the European Pharmaceutical Marketing Research Association ('EphMRA') maintain ATC systems. They are virtually identical. In merger cases, the Commission has tended to use the EphMRA system since this is the system by reference to which European market statistics are gathered and reported by IMS.

18 The first level typically refers to the anatomical group, the second level to the therapeutic subgroup, the third level to the therapeutic and pharmacological subgroup, the fourth level to the therapeutic, pharmacological and chemical subgroup and the fifth level to the

specific chemical substance.

19 Eg method of administration, first line versus second line products, plain versus combined products.

20 For example, in Case M.2922 *Pfizer/Pharmacia*, the Commission considered the G4B category ('Other Urological Preparations') as too broad in order to classify Pfizer's Viagra, since the pharmaceuticals forming part of this ATC-3 classification had clearly differing therapeutic indications. The relevant market was defined as the market for Erectile Dysfunction at ATC-4 level, G4B3.

21 Frédéric Jenny, *Pharmaceuticals Competition and Free Movement of Goods*.

22 Case 27/76, *United Brands v Commission*, 1978 ECR I-207.

23 See footnote 32 below.

24 Simon Bishop and Mike Walker, *The Economics of EC Competition Law*, op cit, p 79.

25 Although there are, to some extent, conflicting studies on what, if any, impact parallel imports have on the retail prices of certain medicines, there appears to be no evidence suggesting that any such price differences would be significant. This should not be surprising, bearing in mind that parallel imports in medicines have come about not as a result of consumer demand but rather due to the arbitrage activity of parallel traders seeking profit from existing price differences.

26 Simon Bishop and Mike Walker, *The Economics of EC Competition Law*, op cit at p 189.

27 Case 85/76, *Hoffmann-La Roche v Commission*, 1979 ECR 461.

28 Simon Bishop and Mike Walker, *The Economics of EC Competition Law*, op cit, p 187.

29 This seems to be confirmed also by the CFI's statement in *Bayer* that "(…) provided he does so without abusing a dominant position, (…), a manufacturer may adopt the supply policy which he considers necessary, even if, by the very nature of its aim, for example, to hinder parallel imports, the implementation of that policy may entail restrictions on competition and affect trade between Member States".

30 Case T-41/96 *Bayer AG v Commission* [2000] ECR II-3383.

31 See Joined Cases 6 and 7-73, *Instituto Chemioterapico Italiano and Commercial Solvents Corporation v Commission*; Case 311/84, *Centre belge d'études de Marché—Télémarketing (CBEM) v SA Compagnie luxembourgeoise de télédiffusion (CLT) and Information publicité Benelux (IPB)*. The rare cases where a refusal to supply a new customer have been condemned, have typically been based on the application of the essential facilities doctrine. However, as one leading commentator suggests, for the doctrine to apply there should be scope for added value competition downstream, not mere resale. It is questionable, therefore, whether the doctrine can be applied to a manufacturer/wholesaler relationship. See John Temple Lang, *Anticompetitive Non-Pricing Abuses under European and National Antitrust Law*, in Hawk (ed) [2004] 26 Fordham Corp L Iust; p 270.

32 The European Commission conducted some research on this as part of its investigations into the supply quota systems adopted by several pharmaceutical manufacturers. It apparently found that, on the parallel traders' own assessment, these systems did not significantly affect their activities. See remarks made by Luc Gyselen, former head of unit responsible for food and pharmaceuticals in DG Comp, at the IBC's annual pharmaceutical conference in May 2004.

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Arnold & Porter opened its Brussels office in August 2003 and it has since expanded to a team of 10 competition/antitrust lawyers. Most recently, Luc Gyselen, a senior official with the Directorate-General for Competition (DG Comp) at the European Commission, joined the office as a partner. Since 1999, Mr Gyselen directed DG Comp's Food and Pharmaceuticals unit, and before that he was head of the financial services unit. Heading the European competition practice from Brussels is EU competition expert Marleen Van Kerckhove. Ms Van Kerckhove and Mr Gyselen are joined by partner Susan Hinchliffe, who is permanently based in Brussels, and Tim Frazer, head of the UK competition practice, who divides his time equally between Brussels and London. The team collaborates with the head of Arnold & Porter's global antitrust practice, William Baer, who is based in Arnold & Porter's DC office but also spends a significant portion of his time in Brussels.