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2008

YEARBOOK of ANTITRUST and REGULATORY STUDIES
www.yars.wz.uw.edu.pl

Peer-reviewed scientific periodical, focusing on legal and economics issues of antitrust and regulation.

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Centre of Antitrust and Regulatory Studies, University of Warsaw, Faculty of Management
www.wz.uw.edu.pl

Parallel Trade in Prescription Medicines in the European Union: The Age of Reason?

by

Ian S. Forrester* QC and Anthony Dawes**

*"**Hamlet:***
Madam, how like you this play?
Queen:
The lady doth protest too much, methinks."
William Shakespeare, *Hamlet Act 3, scene 2.*

Introduction

European competition law, uniquely in the world, attributes high importance, and uses the competition rules, to achieve market integration. In the early years, EC competition decisions punished manufacturers and resellers who contractually inhibited parallel traders. Such actions may have rewarded "free riders" but also helped to create consumer awareness of cross-border shopping opportunities. However, the case of prescription medicines is different.

Parallel trade in prescription medicines, unlike parallel trade in other products, is driven by discrepancies between how Member States set prices. Member States individually choose whether to set higher prices, which will support research and development (R&D), employment and the emergence of new medicines, or whether to set lower prices and thus reduce the pressure on national health budgets. Neither of these two policies is right or wrong, but they result in very

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** White & Case, Brussels. The above disclaimer applies.

different price levels across the EU, thereby creating disparities which parallel traders are able to exploit. That trade, though economically irrational, is as a matter of Community policy, perfectly legal and highly profitable for the wholesalers.

The European pharmaceutical industry has therefore argued that since such price regulation distorts normal conditions of competition in the sector, the industry should be entitled to adopt measures reacting to – but not prohibiting or eliminating – parallel trade, and that such measures should not be considered contrary to the European Community ("EC") competition rules[1]. By contrast, parallel traders[2], the European Commission ("the Commission") and certain Member States[3] have maintained that the pharmaceutical industry cannot seek to adopt measures preventing parallel trade in prescription medicines as to do so would run contrary to one of the fundamental (and unique) goals of EC competition law.

These issues are of great economic importance and legal interest. This paper will therefore review some of these controversies and show that the specific legal and economic context in which the European prescription medicines sector operates sets parallel trade in prescription medicines apart from parallel trade in other goods. We argue that this specific context should entitle pharmaceutical companies to adopt proportionate measures to react to such parallel trade.

The specific and legal economic context in which parallel trade in prescription medicines takes place sets the sector apart from trade in other goods

Parallel trade is not needed by payers to reduce the price of prescription medicines

Parallel trade is conventionally considered to make markets more efficient, which brings about lower prices for consumers and introduces inter-brand price competition. In the case of prescription medicines, however, there is

[1] See European Federation of Pharmaceutical Industries and Associations ('EFPIA'), *Competition Policy in the Pharmaceutical Sector – Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?*, Research Project, November 2004, accessible at: http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=4354.

[2] See European Association of Euro-Pharmaceutical Companies ('EAEPC'), *Understanding Competition in the Distribution of Pharmaceutical Products in Europe: An Analysis of the Application of Article 82 EC to Supply-restrictions in the Pharmaceutical Sector*, September 2005, accessible at: http://www.eaepc.org/admin/files/eaepc_article_82_study_september_2005.pdf.

[3] The Republic of Poland has intervened in both the *GlaxoSmithKline Services Unlimited* appeals (Cases C-501/06 P, *GlaxoSmithKline Services Unlimited v Commission* and C-513/06 P, *Commission v GlaxoSmithKline Services Unlimited*, pending) and *Lelos* preliminary references (Joined Cases C-468-478/06 *Sot. Lelos kai Sia EE and Others v. GlaxoSmithKline Anonimi Emporiki Viomikhaniki Etairia Farmakeftikon Proionton*, judgment of 16 September 2008, not yet reported).

effectively no price competition at patient level. Patients do not "shop around" for the cheapest prescription medicine since the State pays all or most of the cost, and sets the price. So there is no intra-brand competition for prescription medicines as there is for sports equipment, food or washing machines. Patients cannot choose between prescribed medicines on the basis of price: each pharmacy charges the same price in accordance with national regulations. Most of the potential "savings" from parallel trade are therefore consumed by intermediaries at either the wholesale or the pharmacy level. Thus, there is no intra-brand price competition in the normal sense.

Parallel trade is also not needed by governmental payers to reduce the price of prescription medicines. They can do it directly. For example, the United Kingdom ("UK") imposed unilateral profit reductions of 4.5% in 1999 and of 7% in 2004 on all prescription medicines delivered by pharmaceutical companies. Germany similarly introduced price cuts on the ex-factory prices of prescription medicines not affected by reference pricing of 6% in 2003, of 16% in 2004 and of 6% in 2005. Other Member States have also imposed similar price cuts: for example Italy (5% in 2002, 7% in 2003, 6.8% in 2004 and over 9% in 2006), Spain (6% in 1999/2000, 4.2% in 2004 and 2% in 2006), etc.

Some Member States have also introduced "claw back" regulations in order to recover part of the windfall profits earned by pharmacies and wholesalers via parallel trade. For example, UK intermediaries engaged in parallel imports were not passing on those profits to patients, who pay the same amount (zero or a fixed prescription fee, depending on the patient) regardless of whether or not a product was parallel-imported. Moreover, the UK health system was reimbursing pharmacies that had purchased prescription medicines from parallel traders at the higher "official" rate for original prescription medicines, regardless of the actual price pharmacies paid to wholesalers. A discount recovery scheme, the so-called "claw back", was therefore established, not in order to encourage parallel trade, but to claw back some of the profits accruing to pharmacists and wholesalers.

Moreover, it seems that the Member States who have put in place such schemes would happily dispense with the alleged savings they receive from parallel trade. In 1999, Mr. Frank Dobson, the then UK Secretary of State for Health, noted that for every pound the National Health System ('NHS') saved through the claw back, £ 6 were lost by the British pharmaceutical industry, which was a "bad bargain" for the UK[4]. Equally, in 2005, the then Health Minister, Jane Kennedy MP, stated that the savings attributable to the claw back were less than 1% of the UK budget for prescription medicines[5].

[4] See Script No. 2428, 14 April 1999, p. 2.

[5] Mrs. Kennedy stated on 6 June 2005 that savings were £60 million in England and Wales.

Consequently, parallel trade of prescription medicines from one Member State to another does not confer on those who pay for medicines significant advantages. Patients and national governments are largely unaffected in what they expend by whether the prescription medicines they get are parallel-imported or not.

The effects of parallel trade of prescription medicines on R&D

Competition in the prescription medicines sector is based around innovation in the development of new medicines. This should ensure that new products reach the market and benefit consumers[6]. It is only through innovation that pharmaceutical companies are able to discover new medicines.

A pharmaceutical company's return on investment is highly dependent on a limited number of products which are increasingly costly to develop and which enjoy a limited period of exclusivity before patent expiry. Those costs were quantified in 2005 in the region of EUR 800 million per commercialised prescription medicine. As only one or two out of 10,000 compounds initially tested make it to the market, successful prescription medicines must therefore pay for the costs of all the other unsuccessful ones.

Moreover, due to the long lead time between the awarding of a patent for a compound and the grant of a marketing authorisation for the medicine[7], coupled with substantial delays in obtaining prices or reimbursement approvals, or both in some countries[8], the period of commercial monopoly where a

[6] Commission Communication COM(1998) 588 final of 25 November 1998 on the Single Market in Pharmaceuticals, pp. 3, 11, 16.

[7] All medicinal products must be evaluated by the relevant competent authorities and approved before they may be sold. The same levels of quality, safety and efficacy must be demonstrated by all medicinal products and in all Member States. See Article 6 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, OJ [2001] L 311/67 and Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ [2004] L 136/1.

[8] In 2004, EFPIA commissioned IMS Health to produce a bi-annual study of delays between marketing authorization and effective patient access to new medicines in different EU Member States. The resulting „Patients' W.A.I.T. Indicator Report" (Waiting to Access Innovative Therapies) reveals substantial differences in patient access to new medicines across the European Union. The latest edition – the Patients' W.A.I.T. Indicator Phase 8 Report published in November 2007 – shows that, for 18 of the 20 European countries covered in the report, 20 to 94% of the medicines that received a marketing authorisation between 1 January 2003 and 31 December 2006 were still not available to patients on 30 June 2007. See http://www.efpia.eu/content/default.asp?PageID=559&DocID=3658.

pharmaceutical company may effectively seek to recoup its investment on a product prior to the expiry of patent protection is as little as eight or nine years[9] as when the compound goes off-patent and generic medicines come on to the market, there is a dramatic fall in price. Pharmaceutical companies launch new patented products in order to earn profit which finances today's R&D in order to discover tomorrow's medicines. According to the European Commission's 2007 scorecard of worldwide corporate investment in R&D[10], the pharmaceutical sector is now the top global investor in R&D and has the highest R&D intensity ratios of all sectors.

In that regard, parallel trade in prescription medicines reduces the profits that pharmaceuticals companies are able to invest in R&D activities. Parallel traders not only make no contribution to pharmaceutical innovation but they reduce the profits of manufacturers in high-cost countries, which, in turn, limits the ability of manufacturers to invest in the R&D of the future.

Parallel trade risks delaying the launch of new medicines

Before a pharmaceutical product can be put on the list for prescription by doctors, its price must be set by the competent public authority. The question arises of whether the company having decided to accept to sell in a Member State like Spain, Greece or Italy at a certain price must also accept to supply at the same price the needs of patients in other countries. If so, this could create a disincentive to launch in low-price countries

> "it is entirely conceivable that, if they cannot negotiate a price increase in low-price Member States, dominant pharmaceutical undertakings would respond to an obligation to supply parallel traders within a given Member State by removing existing products from the market in that State, if they were able to do so, and by delaying the launch of new products there. Price differentials would be replaced by a greater fragmentation of the market, with a differing range of products available from State to State"[11].

Certain patients in some low-priced Member States would therefore have limited or no access to the newest medicines, something which is neither the

[9] So-called Supplementary Protection Certificates ("SPCs") prolong patent duration, but it remains true that the overall period is short. See Council Regulation No (EEC) 1768/92, of 18 June 1992, concerning the creation of a supplementary protection certificate for medicinal products, OJ [1992] L 182/1.

[10] Accessible at: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1448&format=HTML&aged=0&language=EN&guiLanguage=en.

[11] Opinion of Advocate General Jacobs delivered on 27 October 2004 in Case C-53/03, *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE*, [2005] ECR I-4609, para. 95.

aim of the pharmaceutical industry, nor should it be that of EC competition law. Indeed, as the ECJ noted in *Lelos*,

> "in the light of the Treaty objectives to protect consumers by means of undistorted competition and the integration of national markets, the Community rules on competition are also incapable of being interpreted in such a way that, in order to defend its own commercial interests, the only choice left for a pharmaceuticals company in a dominant position is not to place its medicines on the market at all in a Member State where the prices of those products are set at a relatively low level"[12].

Similarly, if it were impossible for pharmaceutical companies to adopt proportionate measures to react to parallel trade, this might have the effect of exporting the pricing policies of Member States which set prices at a lower level and imposing them on Member States which set prices at a higher level in order to support R&D, employment and the emergence of new medicines.

As a result, while a pharmaceutical company is free to put on the market a product in a Member State on the basis of the price proposed by the Member State authorities, it cannot be the case that, if it has chosen to put a product on the market at a given price, it must then accept to supply patients across the EU at that same price.

Parallel trade and increased risks relating to the entry into the legitimate supply chain of counterfeit medicines

There have also been a number of recent controversies concerning parallel trade and the entry into the legitimate supply chain of counterfeit prescription medicines. According to the Commission, there has been a sharp increase in seized counterfeit medicines in recent years. Statistics report the seizure of 2 711 410 medicinal products at EU customs borders in 2006, an increase of 384% compared to 2005[13] and of 4 081 056 in 2007, a further increase of 51% compared to 2006[14].

Counterfeit medicines are commonly made in countries outside the EU. Sometimes they contain diluted active ingredient and sometimes they contain

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[12] Judgment in Joined Cases C-468/06-478/06, para. 68.

[13] Report on Community customs activities on counterfeit and piracy – results at the European border – 2006, accessible at: http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf

[14] Report on Community customs activities on counterfeit and piracy – results at the European border – 2007, accessible at: http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf

no active ingredient at all. Common targets for such fraudulent activity are prescription medicines for cardiovascular diseases or erectile dysfunction.

The multiplicity of repackaging and re-boxing and re-labelling procedures which parallel trade involves can make it easier for fraudulent operators to introduce into the supply chain boxes of product which look almost identical to the genuine product to the unpractised eye. For example, on 24 May 2007, the UK regulatory authority (the Medicines and Healthcare products Regulatory Agency or MHRA) issued four separate Drug Alerts following the discovery of multiple batches of counterfeit cancer, cardiovascular and psychiatric prescription medicines in the parallel supply chain in the UK. All the counterfeit tablets had been supplied in French livery and the packaging had been over-labelled and/or replaced for sale in the UK as parallel imported products[15].

The risk of counterfeits entering the legitimate supply chain is an increasingly serious issue, so serious that the Commission, as part of the broader public debate on the future of pharmaceuticals in Europe, is analysing "patients' safety aspects of prescription medicines in the distribution chain, including aspects related to parallel trade and to counterfeiting of prescription medicines"[16]. Moreover, as Enterprise Commissioner Verheugen stated on 15 January 2008, in response to a parliamentary question[17], the first results of the Commission's study show that the repackaging linked to parallel trade poses a "considerable risk" for the safety of the patients. He explained that "[t]he reasons for that are numerous e.g. there are problems with the packaging and labelling of the products as well as with product recalls, the complexity of the distribution channels and the supply." As a result, the Commissioner announced that the Commission will prioritise this issue and issue a legislative proposal to tackle counterfeits, which is scheduled for adoption before the end 2008.

Finally, the Commission has also recently published the results of a study commissioned in 2006 from Europe Economics[18], which confirms that the "system of parallel trade in patented medicines under present legislation is

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[15] For more details, see C. Stothers, "Counterfeit Pharmaceuticals Enter The Parallel Supply Chain" (2007) 2 *Journal of Intellectual Property Law & Practice* 797.

[16] *The Future of Pharmaceuticals for Human Use in Europe*, accessible at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_07/consultationpaper-2007-07-19.pdf.

[17] Oral Question for Question Time at the part-session in January 2008 pursuant to Rule 109 of the Rules of Procedure of the European Parliament by Mairead McGuinness MEP, H-0980/07, accessible at: http://www.europarl.europa.eu/sides/getDoc.do?type=CRE&reference=20080115&secondRef=ITEM-017&language=EN#2-245

[18] *Safe Medicines through Parallel Trade*, 13 May 2008, accessible at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_10/report13may_corr.pdf

damaging to patients in a number of ways"[19] and that these "main adverse results are systemic, and not the result of failings by individual businesses or regulators"[20]. The study therefore concludes that

> "the clearly preferable policy option would be to legislate to prohibit repackaging and re-labelling, and to ensure that the original packaging is not opened before the pack reaches the patient. This would result in a dramatic reduction in the level of parallel trade and in the loss or redeployment of some 10,000 jobs. It would however remove the harm to patients that results from parallel trade, improve the operation of the EU Single Market by making it possible for increased supplies of medicines to be purchased by healthcare providers in lower-income Member States, and contribute positively to other EU objectives including the Lisbon Strategy for a more competitive economy, improved environmental policy, and better regulation"[21].

We submit that it is interesting to consider whether the risks to patient health and safety of widespread and unsupervised repackaging of prescription medicines are outweighed by the economic advantages conferred upon those engaging in parallel trade. The precautionary principle has regularly been invoked to justify prohibitions even where there are modest health risks to the public[22].

The specific and legal economic context of the European prescription medicines sector entitles companies to adopt proportionate measures to react to the challenges created by parallel trade

The case law of both Community and national courts has increasingly recognised that, in light of the economic reality, pharmaceutical companies are entitled to appropriate measures responding to the unusual problems presented by parallel trade in prescription medicines.

Relevant Community law precedents

Bayer (Adalat)

The first noted EC judicial pronouncement in the modern phase which we will describe was *Bayer (Adalat)* where the Court of First Instance ("CFI") called into question the appropriateness of the Commission stretching the

[19] Para. 4 of the Executive Summary of the Study.

[20] Para. 7 of the Executive Summary of the Study.

[21] Para. 10 of the Executive Summary of the Study.

[22] Communication from the Commission on the Use of the Precautionary Principle, COM(2000) 1 final. For more discussion of the precautionary principle, see I. Forrester, "The Dangers of Too Much Precaution" [in:] M. Hoskins, W. Robinson (eds.), *A True European: Essays for Judge David Edward*, Oxford/Portland, 2003.

concept of agreement under Article 81(1) EC for the purpose of attempting to bring about market integration in the prescription medicines sector.

In the 1980s and early 1990s, Bayer pursued a system of limiting supplies of its medicinal product Adalat to certain wholesalers in France and Spain. Bayer's system consisted of refusing or reducing orders from "notorious" individual wholesalers, with a view to denying to likely exporters supplies they would sell in higher-price countries. Thus the policy was intended to reduce exports, and this intention was known in the marketplace. Bayer's posture would for many lawyers have appeared risky on the theory that its offers to sell were subject to an unwritten but well known term.

Indeed, these risks were confirmed in January 1996 when, the Commission adopted a decision[23], considering that there was an unwritten export prohibition well known and reluctantly agreed to by wholesalers, which had been part of the "continuous commercial relations" between Bayer France and its wholesalers since at least 1991, and between Bayer Spain and its wholesalers since at least 1989. The Commission asserted there was an agreement between Bayer and its wholesalers in that Bayer's policy was conveyed to the traders by many indicators.

In its judgment, the CFI overturned the Commission's findings, making clear that.

> "the proof of an agreement between undertakings within the meaning of Article [81(1)) of the Treaty must be founded upon the direct or indirect finding of the existence of the subjective element that characterises the very concept of an agreement, that is to say a concurrence of wills between economic operators on the implementation of a policy, the pursuit of an objective, or the adoption of a given line of conduct on the market, irrespective of the manner in which the parties' intention to behave on the market in accordance with the terms of that agreement is expressed (…) The Commission misjudges that concept of the concurrence of wills in holding that the continuation of commercial relations with the manufacturer when it adopts a new policy, which it implements unilaterally, amounts to acquiescence by the wholesalers in that policy, although their de facto conduct is clearly contrary to that policy."[24]

Paragraph 174 of the judgment goes even further:

> "It follows that in the context of that article (Article 81(1), formerly 85(1)), the effects on the conduct of an undertaking on competition within the common market may be examined only if the existence of an agreement, a decision of an association of undertakings or a concerted practice within the meaning of Article [81(1)] of the Treaty has already been established (…) It follows that the aim of that provision is

[23] Commission Decision 96/478/EC of 10 January 1996 relating to a proceeding under Article [81] of the EC Treaty (Case IV/34.279/F3 – *Adalat*), OJ [1996] L 201/1.

[24] Case T-41/96, *Bayer AG* v. *Commission*, [2000] ECR II-3383, para. 173 of the judgment.

> not to eliminate obstacles to intra-Community trade altogether; it is more limited, since only obstacles to competition set up as a result of a concurrence of wills between at least two parties are prohibited by that provision."

The CFI also criticised the Commission for stretching the scope of Article 81(1) EC to bring about market integration in the prescription medicines sector. The CFI stated that "under the system of the Treaty 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 competition rules, "especially since that Treaty gives the Commission 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"[25]. The CFI also considered that the Commission's conviction that parallel trade would harmonise prices for prescription medicines was "devoid of all foundation"[26].

On appeal, the European Court of Justice ("ECJ") upheld the CFI's judgment[27], ruling more cautiously that an agreement for the purposes of Article 81(1) EC "cannot be based on what is only the expression of a unilateral policy of one of the contracting parties, which can be put into effect without the assistance of others"[28]. Moreover, the mere concomitant existence of an agreement which is in itself neutral, and a measure restricting competition that has been imposed unilaterally, does not amount to an agreement prohibited by Article 81(1) EC. Consequently, the ECJ held that

> "the mere fact that a measure adopted by a manufacturer, which has the object or effect of restricting competition, falls within the context of continuous business relations between the manufacturer and its wholesalers is not sufficient for a finding that such an agreement exists"[29].

The result of Bayer (Adalat) is therefore that pharmaceutical companies may reduce the quantities of products they supply to wholesalers, provided that they do so unilaterally.

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[25] Ibid, para. 179.

[26] Ibid, para. 181.

[27] Joined Cases C-2/01 P and C-3/01 P, *Bundesverband der Arzneimittel-Importeure eV and Commission* v. *Bayer AG*, [2004] ECR I-23.

[28] Ibid, para. 101.

[29] Ibid, para. 141.

GSK Spain

In June 2006, the CFI partially annulled a Commission decision[30] that had found that Glaxo Wellcome's, GlaxoSmithKline's ("GSK") predecessor, General Sales Conditions in Spain, which had been notified to the Commission, had the object and the effect of restricting competition and GSK did not demonstrate that they contributed to the promotion of technical progress, the first necessary condition for exemption under Article 81(3) EC.

This has been referred to as the "dual pricing" case, but this is a misnomer, as in reality GSK only set the price of prescription medicines either not reimbursable or not sold in Spain. By contrast, the price for prescription medicines which are reimbursable and sold in Spain is set under Article 100 of Spanish Law 25/1990 (now Article 90 of Spanish Law 29/2006) i.e. by the Spanish State and not by GSK.

In its judgment[31], the CFI, after noting that competition between pharmaceutical companies is based on innovation rather than price[32], considered that the applicability of Article 81(1) EC cannot depend merely on whether an agreement may limit parallel trade but on whether its object or effect may limit competition to the detriment of the final consumer[33].

> "Consequently, while it is accepted that an agreement intended to limit parallel trade must in principle be considered to have as its object the restriction of competition, that applies in so far as the agreement may be presumed to deprive final consumers of those advantages … However, if account is taken of the legal and economic context in which GSK's General Sales Conditions are applied, it cannot be presumed that those conditions deprive the final consumers of medicines of such advantages. In effect, the wholesalers, whose function, as the Court of Justice has held, is to ensure that the retail trade receives supplies with the benefit of competition between producers are economic agents operating at an intermediate stage of the value chain and may keep the advantage in terms of price which parallel trade may entail, in which case that advantage will not be passed on to the final consumers"[34].

The CFI further noted that price differences between Member States are a structural consequence of differences in national regulatory regimes[35].

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[30] Commission Decision 2001/791/EC of 8 May 2001 (*Glaxo Wellcome*), OJ [2001] L 302/1.

[31] Case T-168/01, *GlaxoSmithKline Services Unlimited v Commission,* [2006] ECR II-2969.

[32] Ibid, para. 106.

[33] Ibid, para. 119.

[34] Ibid, paras. 121–122.

[35] Ibid, para. 127.

> "[T]he prices of the products in question, which are subject to control by the Member States, which fix them directly or indirectly at what they deem to be the appropriate level, are determined at structurally different levels in the Community and, unlike the prices of other consumer goods to which the Commission referred in its written submissions and at the hearing, such as sport items or motor cycles, are in any event to a significant extent shielded from the free play of supply and demand. That circumstance means that it cannot be presumed that parallel trade has an impact on the prices charged to the final consumers of medicines reimbursed by the national sickness insurance scheme and thus confers on them an appreciable advantage analogous to that which it would confer if those prices were determined by the play of supply and demand"[36].

The CFI therefore concluded that the price of prescription medicines, set by national governments in function of their own choices concerning budget, public health, encouragement of investment and other public policy considerations lies "structurally outside the play of supply and demand and is established at structurally different levels throughout the Community"[37]. This means that, according to the CFI, "[a]s the prices of the medicines concerned are to a large extent shielded from the free play of supply and demand owing to the applicable regulations and are set or controlled by the public authorities, it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers"[38].

Consequently, while an agreement is caught by Article 81(1) EC in so far as it may be presumed to harm final consumers, the CFI found that this cannot be assumed in relation to the parallel trade of prescription medicines in Europe. Rather, the specific context of the prescription medicines sector makes it necessary for the Commission to undertake an effects-based analysis under Article 81(1) EC.

In that regard, while the CFI ultimately upheld the Commission's subsidiary conclusion that the notified agreement restricted competition by effect[39], the CFI went on to annul the part of the Commission Decision that rejected GSK's request for an exemption under Article 81(3) EC, because the Commission had not appropriately addressed GSK's "relevant, reliable and credible" arguments about the effects of parallel trade on its R&D in perhaps the most innovation-driven industry[40].

In so doing, the Court discussed at some length the special characteristics of the prescription medicines sector, in particular, the importance of competition

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[36] Ibid, paras. 133 and 134.
[37] Ibid, para. 141.
[38] Ibid, para. 147.
[39] Ibid, paras. 165–192.
[40] Ibid, para. 263 et seq.

by innovation. The CFI accepted that parallel trade represented a clear reduction of the possibility of pharmaceutical companies to invest more in R&D:

> "[P]arallel trade has the effect of reducing [research & development-destined] income, to an uncertain but real degree. That practice, which economists know as 'free riding', is characterised by the fact that the intermediary leaves the role which he traditionally plays in the value chain and becomes an arbitrageur and thus obtains a greater part of the profit. The legitimacy of that transfer of wealth from producer to intermediary is not in itself of interest to competition law, which is concerned only with its impact on the welfare of the final consumer. In so far as the intermediary participates in intrabrand competition, parallel trade may have a pro-competitive effect. In the medicines sector, however, that activity is also seen in a special light, since it does not bring any significant added value for the final consumer"[41].

By contrast, if GSK were allowed to impose certain limitations on parallel trade, these would be beneficial for innovation:

> "The fact that the profit is retained by the producer will in all likelihood give rise to a gain in efficiency by comparison with the situation in which the profit is shared with the intermediary, because a rational producer which is able to ensure the profitability of its innovations and which operates in a sector characterised by healthy competition on innovation has every interest in reinvesting at least a part of its surplus profit in innovation"[42].

The CFI's judgment is currently under appeal to the ECJ[43].

Syfait

Syfait was the first case in which the ECJ was requested to provide guidance on the application of Article 82 EC to unilateral conduct of pharmaceutical companies intended to react to parallel trade in prescription medicines.

The case stemmed from complaints lodged in 2000 and 2001 with the Hellenic Competition Commission ("HCC") by a number of wholesalers, alleging that by limiting supplies of certain drugs from its Greek subsidiary, GSK was abusing its dominant position, contrary to Article 82 EC. The wholesalers in question had been addressing ever-larger orders for prescription medicines to GSK Greece, mainly for export, to exploit the price differentials in prescription medicines between EU Member States. In 2000 GSK, for one

[41] Ibid, para. 273.

[42] Ibid, para. 274.

[43] Cases C-501/06 P, *GlaxoSmithKline Services Unlimited v Commission*; C-513/06 P, *Commission v GlaxoSmithKline Services Unlimited*; C-515/06 P, *EAEPC v GlaxoSmithKline Services Unlimited*; and C-519/06 P, *Aseprofar v GlaxoSmithKline Services Unlimited*.

product, had reached the point of supplying seven times Greek demand, yet shortages persisted on the Greek market. GSK therefore took the decision to suspend supplies to wholesalers for a few weeks to ensure that pharmacy supplies were restored. Subsequently, it decided to supply wholesalers with quantities corresponding to Greek annual consumption plus a safety margin (amounting to 25% of annual Greek consumption).

The HCC referred the case to the ECJ, asking whether the refusal by GSK to supply, in unlimited quantities, all the orders placed by wholesalers, could constitute an abuse of a dominant position, in light of the fact that "parallel trade is particularly profitable for the wholesalers because of the different prices, resulting from State intervention, in the Member States of the European Union, that is to say by the fact that pure conditions of competition do not prevail in the pharmaceuticals market, but a regime which is governed to a large extent by State intervention".

In his Opinion, Advocate General Jacobs considered that a pharmaceutical undertaking holding a dominant position does not necessarily abuse that position by refusing to meet in full the orders sent to it by wholesalers, even if that action will limit parallel trade. In reaching this conclusion, the Advocate General referred in particular to:

- the pervasive and diverse state intervention in the pricing of prescription medicines, which is responsible for price differentials between the Member States[44];
- the regulation by the Community and the Member States of the distribution of prescription medicines, which imposes nationally demarcated obligations upon pharmaceutical undertakings and wholesalers to ensure the availability of adequate stocks of those products[45];
- the potentially negative consequences of parallel trade for competition, the common market, and incentives to innovate, given the economic characteristics of the pharmaceutical industry[46]; and
- the fact that end consumers of prescription medicines may not in all cases benefit from parallel trade, and that public authorities in the Member States, as the main purchasers of such products, cannot be assumed to benefit from lower prices, given that they are themselves responsible for fixing prices within their territories[47].

As a result, the Advocate General concluded that because of the specific characteristics of the European prescription medicines sector, GSK could not

[44] Opinion of Advocate General Jacobs delivered on 27 October 2004, paras. 77–79.
[45] Ibid, paras. 80–82.
[46] Ibid, paras. 89–95.
[47] Ibid, paras. 96–99.

be said to have abused its dominant position[48]. Furthermore, the Advocate General agreed that the parallel trade of prescription medicines does not necessarily result in any substantial benefits for ultimate consumers of such medicines.

The Grand Chamber of the ECJ never proceeded to a final ruling on the merits of that case, since it considered the reference to be inadmissible on the grounds that the HCC was not a court or tribunal for the purpose of Article 234 EC. Advocate General Jacobs's Opinion was, however, followed by the Hellenic Competition Committee in its decision of 1 September 2006 on the merits[49]. It held that GSK had not breached Article 82 EC and more specifically it had not abused its dominant position by refusing to supply the wholesalers to fuel parallel exports: there was no abuse of dominance, either for the October 2000-February 2001 period, when GSK had put in effect a system of direct supply of pharmacies and hospitals, or for the period after February 2001, when it had resumed supplies to wholesalers on the basis of a quota system.

The HCC's conclusion as to the non-applicability of Article 82 EC was based on, *inter alia*, the following reasons:

> "(a) the fact that in the European pharmaceutical sector no strict competition conditions apply, due to state interventionism in the price-fixing of pharmaceuticals, (b) the percentage by which the quantities supplied by the dominant undertaking exceeded national consumption, (c) the effect of parallel trade on the profit of the dominant undertaking, (d) the lack of any benefit for the end consumer entailed by parallel trade and (e) the overall economic and regulatory context of the decision"[50].

Lelos

In 2006, the Athens Civil Court of Appeal referred to the ECJ, the same questions, based on the same facts, as those already referred by the HCC in *Syfait*.

The case was argued before the Grand Chamber of the ECJ in January 2008 and Advocate General Colomer delivered his Opinion on 1 April 2008. While he agreed with Advocate General Jacobs that there can be no *per se* abuse of Article 82 EC, even where a dominant undertaking has deliberately sought to restrict parallel trade, Advocate General Colomer contended that such a subjective intention "*can often indicate that an anticompetitive outcome*

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[48] Ibid, paras. 101–102

[49] Decision 318/V/2006 of 1 September 2006, accessible at: http://www.epant.gr/Apofaseis.php3.

[50] Ibid, Section VI.i.b, point 3.

is being sought[51]" and may constitute an aggravating factor contributing to the presumption that such behaviour was abusive[52].

Advocate General Colomer also refused to accept that state intervention through price setting or the imposition of public service obligations to ensure adequate national supply of patients may constitute an objective justification for such an abuse. On the contrary, the Advocate General considered that even though "the pharmaceuticals market does not operate under normal competitive conditions", pharmaceutical companies retain a certain margin of manoeuvre to negotiate prices with the Member States[53] and that the duty to ensure adequate supplies to national patients does not justify cutting off supplies to "rival" wholesalers, because the needs of patients in Member States are not subject to sudden change and statistics for various illnesses are reliable, offering companies a degree of predictability which enables them to adapt to market demands[54].

Finally, Advocate General Colomer rejected as "misleading" the contention that the protection of a pharmaceutical company's legitimate business interests may justify its conduct and that there is any causal link between the losses sustained by pharmaceutical companies due to parallel trade and their investment in R&D. In his words, these arguments were "aimed only at seducing public opinion, which is sensitised to the vital importance of R&D for competitiveness, by shifting the focus from business rivalry to research policy."[55] The Advocate General felt that GSK had not indicated any positive effects resulting from its refusal to supply prescription medicines to Greek wholesalers[56].

The ECJ's judgment was therefore awaited with particular interest as the Court had before it contrasting Opinions from two of its Advocate Generals on the same legal issue.

On the one hand, the ECJ considered some of the policy arguments which the pharmaceutical industry has traditionally put forward in order to justify imposing limits on parallel trade.

First, the judgment confirms that a pharmaceutical company is abusing its dominant position if it refuses to meet ordinary orders by wholesalers of prescription medicines in order to prevent parallel exports. This principle is not new, although it was extensively commented upon[57].

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[51] *Lelos*, Opinion of 1 April 2008, para. 49.
[52] Ibid, paras. 50–51.
[53] Ibid, para. 93.
[54] Ibid, para. 96.
[55] Ibid, para. 113.
[56] Ibid, para. 118.
[57] Judgment in Joined Cases C-468/06-478/06, para. 66.

Second, the ECJ found that parallel trade does create some benefits both by exerting "pressure on prices" and opening up an alternative source of supply for purchasers[58].

Third, the ECJ doubted that state intervention in the prescription medicines sector means that pharmaceutical companies have no influence upon the level at which prices are set and that such intervention entirely removes the prices of prescription medicines from the forces of supply and demand[59].

Fourth, the Court considered that "where a medicine is protected by a patent which confers a temporary monopoly on its holder, the price competition which may exist between a producer and its distributors, or between parallel traders and national distributors, is, until the expiry of that patent, the only form of competition which can be envisaged"[60].

Fifth, in situations where parallel exports lead to shortages in the Member State of export, it is for the competent health authorities of that Member State, and not for dominant pharmaceutical companies, to take the appropriate and proportionate steps to address such shortages[61].

On the other, the judgment contains important and welcome statements confirming that pharmaceutical companies are entitled to adopt measures responding to the unusual problems presented by parallel trade in prescription medicines.

First, the Court accepted that the "price differences between Member States for certain medicines are … the result of the different levels at which the prices and/or the scales to be applied to those medicines are fixed" by the State and not due to other parameters, such as currency fluctuations[62], something which the European Commission and parallel traders had not been willing to concede.

Second, the Court rejected the argument that once a pharmaceutical company decides to put its product on the market in a certain Member State at the price set by the State, it can no longer take any measures to protect its interests:

> "In the light of the Treaty objectives to protect consumers by means of undistorted competition and the integration of national markets, the Community rules on competition are also incapable of being interpreted in such a way that, in order to defend its own commercial interests, the only choice left for a pharmaceuticals company in a dominant position is not to place its medicines on the market at all

[58] Ibid, paras. 53–56.
[59] Ibid, paras. 61–63.
[60] Ibid, para. 64
[61] Ibid, para. 75.
[62] Ibid, para. 59.

in a Member State where the prices of those products are set at a relatively low level"[63].

Finally, the Court made clear that a dominant pharmaceutical company must be in a position to take steps that are reasonable and in proportion to the need to protect its own commercial interests:

"although a pharmaceuticals company in a dominant position, in a Member State where prices are relatively low, cannot be allowed to cease to honour the ordinary orders of an existing customer for the sole reason that that customer, in addition to supplying the market in that Member State, exports part of the quantities ordered to other Member States with higher prices, it is none the less permissible for that company to counter in a reasonable and proportionate way the threat to its own commercial interests potentially posed by the activities of wholesalers which wish to be supplied in one Member State with significant quantities of products that are essentially destined for parallel export"[64].

In particular, a dominant pharmaceutical company must able to protect its own commercial interests when confronted with orders that are out of the ordinary, in light of both the previous business relations and the requirements of the market in the relevant Member State:

"a producer of pharmaceutical products must be in a position to protect its own commercial interests if it is confronted with orders that are out of the ordinary in terms of quantity. Such could be the case, in a given Member State, if certain wholesalers order from that producer medicines in quantities which are out of all proportion to those previously sold by the same wholesalers to meet the needs of the market in that Member State"[65].

Relevant national decisions and academic literature also support the proposition that the pharmaceutical industry is entitled to take reasonable and proportionate steps to respond to parallel trade

National courts and competition authorities across the EU have also concluded that the pharmaceutical industry is entitled to take reasonable and proportionate steps to respond to parallel trade.

In France, the Competition Council has found that "the correct application of competition law requires to take into account completely the existence of price regulation"[66] and that accordingly "we fail to see what justification

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[63] Ibid, para. 68.

[64] Ibid, para. 71.

[65] Ibid, para. 76.

[66] Case 05-D-72 of 20 December 2005 *relative à des pratiques mises en oeuvre par divers laboratoires dans le secteur des exportations parallèles de médicaments*, para. 269, authors' own

would allow an economic operator to impose on a producer who does not dispose of the freedom to fix the price of its products intended to be used on a territory, to apply in a general way the same terms of sale for products intended exclusively for other territories where the conditions of market are different"[67].

This decision was confirmed by the Paris Court of Appeal, which found that "in light of the particular situation that prevails in France, it is not excessive for a pharmaceutical company to defend its commercial interests by refusing to deliver its products set at a fixed price administered to an operator who sells no product on the national market for which the price has been fixed and who seeks to obtain this product only on condition that the price fixed by the authorities in view of its use on in the national territory allows it to resell the product) on a foreign market with profit"[68].

In Spain, the Competition Tribunal[69] has held that it is not right to say that "pharmaceutical companies enjoy independence in freely determining their prices, because Spanish legislation is governed by a system of price intervention of pharmaceuticals, which must be authorised by the Administration in all stages of their marketing". Moreover, a judgment of Spain's second highest court (the Audiencia Nacional), has declared that "parallel exports mainly benefit wholesalers, who obtain disproportionate, unexpected and exceptionally high profits ("wind-fall profits"). In other terms, parallel exports do not constitute any direct benefit for consumers that pay the same price for the pharmaceutical product, whether it originates or not from a parallel import"[70].

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translation from the French original: "*la bonne application du droit de la concurrence nécessite de prendre pleinement en compte l'existence d'une réglementation des prix*".

[67] *Ibid*, para. 267, authors' own translation from the French original: "*on ne voit pas quelle justification permettrait à un opérateur économique d'imposer à un producteur qui ne dispose pas de la liberté de fixer ses prix pour les produits destinés à être utilisés sur un territoire, d'appliquer d'une manière générale les mêmes conditions de vente pour des produits destinés exclusivement à d'autres territoires où les conditions de marché sont différentes*".

[68] 1st Chamber, Section H, Judgment of 23 January 2007, authors' own translation from the French original: "*au vu de la situation particulière que prévaut en France (…) il n'est pas abusif pour un laboratoire de défendre ses intérêts commerciaux en refusant de livrer ses produits à un prix administré à un opérateur qui ne vend aucun produit sur le marché national pour lequel la réglementation du prix a été élaborée et qui ne recherche ce produit qu'à la condition que le prix fixé par les pouvoirs publics en vue d'un usage sur le territoire national lui permette de le revendre sur un marché étranger avec profit*".

[69] Resolution of 5 December 2001, Expte. R 488/01, *Laboratorios Farmacéuticos*.

[70] Judgment of the *Audiencia Nacional* of 26.1.2005 (appeal nº 364/2001), authors' own translation from the Spanish original: "*las exportaciones paralelas benefician principalmente a los mayoristas, que obtienen ganancias desproporcionadas, inesperadas y excepcionalmente elevadas ("wind-fall profits"). Es decir, las exportaciones paralelas no representan ningún beneficio directo*

In Greece, a series of decisions and judgments have also made similar findings.

First, as noted above, the HCC, in the aftermath of the *Syfait* preliminary reference, duly adopted Advocate General Jacobs's findings, and concluded that there was no Article 82 EC violation and that GSK had not abused its dominant position by introducing a quota system for its supply of prescription medicines to Greek wholesalers.

Second, the Athens Court of Appeals reversed the only ruling out of 17 cases, which had found that GSK had abused its dominant position under both Greek and EC competition law by refusing to supply Pharmacon D. Politis, a local wholesaler, with certain prescription drugs destined for export to the United Kingdom[71]. The Court of Appeals held that GSK's conduct was not abusive and placed emphasis on the fact that the Greek State set the price for all prescription drugs at the lowest level in the EU. In the Court's view, no negative effects on the Greek market were proven and parallel trade brought no benefit to final consumers. At the same time, according to the Court, GSK had to protect its legitimate interests. Prices were set only for Greece, in the Court's words.

Third, and in a separate development, the Greek Supreme Court, (the "Areios Pagos") handed down its judgment in the *Servier*[72] case, in which it concluded that Servier's quota schemes were not a violation of Greek/EC competition law. The Supreme Court noted *inter alia* the profits that the wholesalers were making due to the fact that the Greek State had set the prices of prescription medicines at the lowest rate in the EU, that there were some shortages in Greece due to the soaring parallel exports and that even the reduced quotas supplied far exceeded Greek demand. The Supreme Court concluded that "the refusal to supply by [Servier] was neither unreasonable, nor abusive, nor contrary to the good morals". Servier's quota system

> "was not intended to restrict competition but rather to protect its economic interests, which were encroached upon by certain wholesalers through their parallel exports, and thus to secure the satisfaction of the local needs of the medicines' import countries, which is not in the least unreasonable or illegal. If this were considered unreasonable, it would be possible for [Servier] to be required to supply unlimited quantities of its products to the appellants, at the free will of the latter, thus essentially supplying all EU-destined products through them, which is of course unacceptable".

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para los consumidores que pagan el mismo precio por el producto farmacéutico, proceda o no de una importación paralela".

[71] Judgment No 7770/2007 of 22 November 2007. This case is part of the *Lelos* line of cases. However, it was never referred because it was procedurally separate. There were also five more cases in which GSK prevailed at first instance and which the wholesalers did not appeal.

[72] Judgment No 1334/2007 of 11 June 2007.

Finally, there is an growing body of academic literature which follows the logic and approves of the *Bayer (Adalat)*, *GSK Services Unlimited* and now *Lelos* judgments[73].

Conclusions

In light of the economic reality, which is increasingly confirmed by relevant judicial authorities, we submit that hindering parallel trade in prescription medicines does not damage patients and national health budgets.

It is therefore to be welcomed that both Community and national case law has confirmed that pharmaceutical companies are entitled to adopt measures responding to – but not prohibiting or eliminating – parallel trade, and such

[73] Compare F. Jenny "Pharmaceuticals, Competition and Free Movement of Goods" [in:] *EU Competition Law and Policy*, *Developments and Priorities,* Hellenic Competition Committee (ed.), Athens Conference, April 19th 2002, Athens, Nomiki Vivliothiki, p. 83–84; P. Rey, J.S. Venit, "Parallel Trade and Pharmaceuticals: A Policy in Search of Itself" (2004) 29 *E.L.R.* 153; Dawes A., "Neither Head nor Tail: The Confused Application of EC Competition Law to the Pharmaceutical Sector" (2006) 27 *E.C.L.R.* 269; V. Korah, *Intellectual Property Rights and the EC Competition Rules*, Oxford/Portland, 2006, p. 149; D. Chalmers, C. Hadjiemmanuil, G. Monti, A.Tomkins, *European Union Law,* Cambridge 2006, p. 999–1000; E. Dieny, "Appréciation au regard du droit communautaire de la concurrence d'un accord visant à réduire le commerce parallèle des médicaments" (2006) *JCP La Semaine Juridique* 2153; R. Eccles, "Parallel Exports in the Pharmaceuticals Sector: Take Nothing for Granted" (2007) 28 *E.C.L.R.* 138–142; H. Calvet, "Commerce parallèle et droit européen : La fin d'un dogme ?" (2007) 10 *Revue Lamy de la Concurrence* 138; L. Souto Soubrier "The Concept of an Agreement and Beyond: How to Block Parallel Imports of Pharmaceuticals to Protect the Heart of Competition" [in:] G. Amato, C.D., p. 81; V. Korah, "Judgment of the Court of First Instance in *GlaxoSmithKline*" (2007) 6 *Competition Law Journal*, p. 101; W-H. Roth, "Möglichkeiten und Grenzen eines einheitlichen Binnenmarktes für Arzneimittel" [in:] J. Schwarze, U. Becker (eds.), *Arzneimittel im Europäischen Binnenmarkt*, *Europarecht Beiheft 2/2007*, Baden-Baden 2007, p. 37–42; P. Behrens, "Parallelhandelsbeschränkungen und Konsumentenwohlfahrt – Zur neueren Rechtsrechung von EuG und EuGH" (2008) 6 *Zeitschrift für Wettbewerbsrecht* 20; V. Junod, "An End to Parallel Imports of Medicines? Comments on the Judgment of the Court of First Instance in *GlaxoWellcome*" (2007) 30 *World Competition* 291; C. Köning, C. Engelmann, "Parallel Trade Restrictions in the Pharmaceutical Sector on the Test Stand of Article 82 EC: Commentary on the Opinion on Advocate General Jacobs in the Case Syfait/Glaxosmithkline", (2005) 25 *E.C.L.R.* 465; R. Smits, "On Parallel Trade and Preliminary Issues – A Healthy Approach to Competition Law Enforcement?" (2006) 33 *Legal Issues of European Integration* 61. See also A. Nikpay, L. Kjølbye and J. Faull [in:] J. Faull, A. Nikpay (eds.), *The EC Law of Competition*, Oxford, 2007, p. 260, viewing the *O2*, *Österreichische Postsparkasse* and *GlaxoSmithKline Services Unlimited* judgments of the CFI broadly in line with the general approach set out in the Commission's Article 81(3) EC Guidelines, which focus on consumer welfare (Commission Notice – Guidelines on the Application of Article 81(3) of the Treaty, OJ [2004] C 101/97).

measures are not contrary to the EC competition rules. Parallel traders had previously been free-riding on case law which referred to sectors and cases that bore no relation to the special features of the European prescription medicines sector. To the extent there is an assumption that parallel trade in Europe safeguards intra-brand competition, the recent case law does not call this assumption into question: on the contrary, it confirms it, while noting that this assumption is inapplicable to the prescription medicines sector in Europe precisely because of that sector's very specific features.

It is therefore to be hoped that the long-running obsession of European competition law with parallel trade in prescription medicines may (at last) be coming to an end.

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