

Parallel Trade Restrictions in the Pharmaceuticals Sector on the Test Stand of Article 82 EC

Commentary on the Opinion of Advocate General Jacobs in the Case *Syfait/GlaxoSmithKline*

University Professor Dr Christian Koenig
and Dr Christina Engelmann*

¹ Dominant position; EC law; Parallel imports; Pharmaceutical industry

I. Introduction

Parallel trade is, in its economic logic, arbitrage trading with goods based on segmented national price regulations.¹ According to the case law of the European Court

* Christian Koenig is director and Christina Engelmann is scientific consultant at the Centre for European Integration Studies "ZEI" at the University of Bonn. This paper is based on an expert assessment commissioned by the European Association of Euro-Pharmaceutical Companies.

1 Pharmaceutical products are purchased in certain states at low prices to be resold in other states with higher price levels in which the same products are also sold by the original manufacturer. This leads to a situation that the manufacturers must compete in the import countries with their own products being sold by parallel traders at a lower price, see also *Koenig/Engelmann/Sander*, GRUR Int. [2001], 919 (920); for a definition of parallel

of Justice ("ECJ") now stretching back over 30 years,² this is cross-border trade which is protected by the principle of the free movement of goods pursuant to Art.28 EC.³ Obstacles to parallel trade based on national regulations are thus only permissible in the case of a recognised justification and subject to the principle of proportionality. Therefore, evoking national brand-name and patent rights or legal restrictions in the market authorisation of pharmaceutical products was thus of no help to drugs manufacturers in preventing parallel trade.⁴ Thus the (original) manufacturers had to find new ways of combating parallel trade—for example by only supplying the wholesalers in the typical export countries such as Greece or Spain with the quantities sufficient to cover their domestic requirements. After the ECJ made it clear at the start of 2004 that unilateral supply restrictions on the part of a company did not constitute a prohibited competition restricting agreement pursuant to Art.81 EC,⁵ the question remains open as to when such behaviour is covered by the prohibition of abusing a dominant position pursuant to Art.82 EC. This question is now awaiting a decision by the ECJ.

The national proceedings concern the supply of Greek pharmaceutical wholesalers by GlaxoSmithKline ("GSK"). With the aim of preventing parallel trade, GSK refused to execute the wholesalers' orders in full and only supplied them with the quantities required for the domestic market.⁶ According to the Greek Competition Commission, GSK holds a dominant position in Greece at least with regard to one of the drugs concerned. This means that within the pending preliminary ruling proceedings, the ECJ only has to clarify whether the supply restrictions applied by GSK constitute an *abusive*

trade see, e.g. *Heinemann*, PharmR [2001] 180; *Hanika*, MedR [2000] 63 (69).

2 Started by the ECJ, Case 16/74, *Centrafarm/Winthrop* [1974] E.C.R. 1183; then the basic judgment, Case 104/75, *de Peijper* [1976] E.C.R. 613 at [12]–[13].

3 For a summary of the ECJ's parallel trade rulings on Art.28 EC see the Communication of the Commission on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, December 30, 2003, COM 2003 (839) final.

4 See also the summary of the Commission Communication, December 12, 2003, cited above at n.5; see also *Koenig/Engelmann/Sander*, GRUR Int. [2001] 919 *et seq.*

5 Case C-2/01 P & 3/01 P, *Bayer/Commission*, EWS [2004] 166, ECJ; Case T-41/96 [2000] E.C.R. II-3383, CFI.

6 This followed a complete cessation of supplies to wholesalers which was then, however, lifted by the Greek Competition Commission with an injunction. GSK then began to supply the wholesalers again but refused to fulfil the orders in full. For the course of the proceedings see Competition Commission Decision August 3, 2001, *Glaxo Wellcome*, GRUR Int. 2002, 534 *et seq.*; see also the summary by Jacobs A.G., Opinion October 28, 2004 in Case C-53/03, *Syfait/GlaxoSmithKline*, at [3] *et seq.*, available on the internet at www.curia.eu.int/en/content/juris/form.htm by entering the case number.

exploitation of a dominant position within the meaning of Art.82 EC. In his Opinion, Jacobs A.G. sets out the previous judgments of the ECJ on supply restrictions by companies occupying a dominant position on the market and comes to the conclusion that a supply restriction cannot be regarded as abusive just because it is aimed at placing a restriction on parallel trade.⁷ After this the Advocate General explains that, in view of the regulatory and economic peculiarities of the pharmaceutical market, he regards the behaviour of GSK as objectively justified.⁸ However, on closer analysis of the previous rulings of the ECJ, taking into account the complementary relationship between the prohibition on abuse of a dominant position (Art.82 EC) and the free movement of goods (Art.28 EC), both conclusions of the advocate general are questionable.

II. Abuse on the basis of the intended market foreclosure

First we must examine the premise of the Advocate General according to which the existing supply restrictions are not necessarily abusive but rather objectively justifiable and thus a matter of weighing up interests. The basis for this conclusion is the general jurisprudence of the ECJ on the question as to what conditions must be fulfilled to oblige a market dominating company to supply its customers or to give them access to its products or services.⁹ In the course of a number of judgments, the ECJ has developed detailed criteria for the assumption of access obligations often summarised under the heading of the "essential facilities doctrine".¹⁰ The basis in each case was a constellation in which a company with a dominant position on an upstream market refused another company access to its products or services in order to avoid entering into competition on a downstream product market. The ECJ proceeds from the assumption that even market dominating companies are, in principle, entitled to take all reasonable measures to protect their business interests.¹¹

7 Jacobs A.G., Case C-53/03, cited above at n.6, [69].

8 Jacobs A.G., Case C-53/03, cited above, [73] *et seq.* and [100].

9 Jacobs A.G., Case C-53/03, cited above at n.6, [54] *et seq.*

10 See, e.g. *Mennicke*, ZHR [1996] 626 at 652; *Deselaers*, EuZW [1995] 563 *et seq.*; critical on the construction of the "essential facilities doctrine" *Müller*, EuZW [1998] 232 (233); specifically on the significance in the telecommunications sector *Koenig/Loetz*, EWS [2000] 377 at 378 *et seq.*

11 Case 27/76, *United Brands/Commission* [1978] E.C.R. 207 at [184]-[194], ECJ. Specifically, the refusal to grant a licence does not represent an abuse *per se*, Case 238/87, *Volvo* [1988] E.C.R. 6211 at [8], ECJ; and Case C-241 & 242/91 P, *RTE and ITP/Commission (Magill)* [1995] E.C.R. I-743 at [49].

Therefore, according to the jurisprudence of the ECJ, alongside the indispensability of the product concerned for the intended purpose (lack of substitutability), a delivery or access obligation requires that the refusal is not objectively justified and is also likely to rule out all competition on the derived (downstream) market.¹² The Advocate General draws the general conclusion from this that refusals to supply are only abusive if they cause serious distortions of competition and are not objectively justifiable.¹³

It must be taken into account here, however, that the supply restrictions applied by GSK exhibit a significant qualitative difference to the other cases of refusal of access to products or services covered by the essential facilities doctrine. As Temple Lang, one of the European "authors" of the essential facilities doctrine, emphasises, the application of this doctrine requires that added value is generated on a downstream market with the help of the upstream product in the form of a derivative product. The added value may, therefore, not be achieved by a mere resale.¹⁴ There is no such product related value added here as the drugs acquired by the wholesalers do not become a different product as a result of resale and the export/import process despite possibly being repacked and receiving a new information leaflet. Therefore, there is a lot to suggest that the so-called essential facilities doctrine cannot even be applied to the relationship between drugs manufacturers and wholesalers. The abusive nature of GSK's behaviour as well as the question about possible justification cannot be judged on the basis of the above-mentioned criteria. The decisive aspect for the charge of abuse in this case consists, rather, in the peculiarity that the market dominating company here *explicitly* makes it clear that it wants to restrict export and thus parallel trade by its behaviour. The pursued agenda of foreclosing the national markets is thus patently obvious. This

12 See also Case 6/73, *Commercial Solvents/Commission* [1974] E.C.R. 223 at [25]; Case 311/84, *CBEM/CLT and IPB* [1985] E.C.R. 3261 at [25] *et seq.*; Case C-241 & 242/91 P, cited above at n.11, [53] *et seq.*; Case C-7/97, *Bronner* [1998] E.C.R. I-7791 at [40]; as well as the most recent judgment in Case C-418/01, *IMS Health* at [34] *et seq.*, in which the occurrence of a new product is demanded as a further condition.

13 Jacobs A.G., Case C-53/03, cited above at n.6, [66].

14 For the application of the essential facilities doctrine Temple Lang demands "[there must be] scope for substantial non-price competition on the [downstream] market, that is, it is not merely simple resale or distribution of products or services, and a refusal to contract would prejudice consumers", Temple Lang, "Anti-competitive Non-Prising Abuses Under European And National Antitrust Law", in, *International Antitrust Law & Policy*, (Hawk ed., Fordham Corp. L. Inst, 2004), p.235 at 270. The requirement of the occurrence of a new product mentioned by the ECJ for the first time in the *Magill* judgment supports this: Case C-241 & 242/91 P, cited above at n.11, [54]; Case C-428/01, cited above at n.12, [48] *et seq.*

was not the case in the decisions cited by the Advocate General.¹⁵ Within the case constellations there, the market dominating company usually justified its refusal of access in terms of capacity aspects or by reference to industrial property rights.¹⁶ None of the essential facilities cases, however, was concerned with the partitioning of national markets. The supply restrictions in this case are directly aimed at preventing trade between states and can thus be termed "hard-core access refusals". The Advocate General does briefly refer to this finality of the national market foreclosure but then proceeds directly to the question of the objective justification of the practice.¹⁷ However, before dealing with the justification it would be appropriate to first examine the question more exactly as to which conclusions can be drawn from the intended and effected market foreclosure for the existence of an abuse within the meaning of Art.82 EC and whether practices aimed at market foreclosure can ever be justified in principle.

1. Market integration as the overriding aim of basic freedoms and competition regulations

In the definition of abuse within the meaning of Art.82 EC it must be observed that the EC competition rules as well as the basic freedoms granted by the EC Treaty are aimed at preventing market foreclosure at the internal borders of the Member States.¹⁸ As early as 1966 in the case of *Consten and Grundig* the ECJ established that—as well as the realisation of undistorted competition—the competition rules also pursue the basic aim of the Treaty to eliminate the barriers between the Member States markets and are thus directed against any corporate measures which would put such barriers back in place.¹⁹ While the basic freedoms prohibit restrictions of market integration by the Member States, Art.81 *et seq.* EC are aimed at preventing corporate measures for market foreclosure.²⁰ The prohibition on abuse contained in Art.82 EC thus supports the effect of

the basic freedoms in promoting the single market. This relationship with the overriding aim of market integration must be taken into account in any interpretation of the abuse prohibition.²¹ Article 82 EC may thus not be interpreted as meaning that market dominating companies can undermine the freedoms guaranteed to participants in the market by the EC Treaty.²²

In its vast jurisprudence on the free movement of goods (Art.28 EC), the ECJ repeatedly criticised state measures which restricted parallel imports from countries with lower drugs prices. The Court always rejected the reference to national brandname or patent rights as a justification for the restriction of parallel imports where they were likely to lead to an artificial partitioning of the markets between Member States.²³ The rulings of the court make it clear that parallel trade as an arbitrage trade protected by the principle of free movement of goods may not be rendered practically impossible by measures which have the effect of foreclosing national markets.

The same protective intention is also reflected in the rulings on Art.82 EC concerning other sectors of the economy: in the case of *British Leyland*, the ECJ deemed unilateral measures by a market dominating company to prevent re-imports of cars to be abusive within the meaning of Art.82 EC. The classification as abuse was based solely on the fact that the measures concerned were an expression of the clear intention to prevent re-imports.²⁴ In the case of *United Brands*, the ECJ made the same judgment on a re-sale prohibition for green bananas.²⁵ Due to the difficulties of transporting ripe bananas, the prohibition on selling green bananas represented a *de facto* prohibition on exports. Due to the intended foreclosure of the national markets, the

15 See n.12 above.

16 See, e.g. Case C-7/97, cited above at n.12, [9] on capacity bottlenecks as well as Case C-241 & 242/91 P, cited above at n.11, [49]; and Case C-418/01, cited above at n.12, [34] *et seq.* on the evocation of industrial property rights.

17 Jacobs A.G., Case C-53/03, cited above at n.6, [71].

18 See also Commission Decision, *Glaxo Wellcome* [2001] O.J. L302/1 [127] *et seq.*; the Decision is currently pending at the CFI, Case T-168/01.

19 Case 56 & 58/64, *Consten and Grundig* [1966] E.C.R. 321, at 388 and 392, with reference to the current Art.81 EC.

20 With regard to this aim of the EC competition rules see also Schröter in *Commentary on the EC Treaty and the Treaty on the Establishment of the EC* (v. d. Groeben/Schwarze, 6th ed. 2003, Vol.2), foreword to Arts 81–89 EC para.2; Bellamy & Child, *European Community Law of Competition* (5th ed. 2001), paras 1-075 and 1-077.

21 The overriding purpose of the prohibition of abuse in opening national markets is also emphasised by Möschel, in Immenga/Mestmäcker, *EC competition law, Commentary*, Vol.1, 1997, Art.86 para.116.

22 The significance of the single market system for the interpretation of Art.82 EC is misconstrued in the study by the European Federation of Pharmaceutical Industries and Associations (EFPIA), *Article 82 EC: Can It Be Applied to Control Sales By Pharmaceutical Manufacturers to Wholesalers?* November 2004, p.59 *et seq.*

23 See Case C-143/00, *Boehringer Ingelheim* [2002] E.C.R. I-3759; = GRUR Int. 2002, 739 [31] *et seq.*; Case C-443/99, *Merck, Sharp & Dome* [2002] E.C.R. I-3703; = EuZW 2002, 542 [23] *et seq.*; Case C-379/97, *Upjohn* [1999] E.C.R. I-6927; = EuZW 2000, 181 [17] *et seq.*, with further reference on the established legal practice; see also the summary in the Communication of the Commission December 30, 2003, cited above at n.3.

24 Case 226/84, *British Leyland/Commission* [1986] 3263 [16], [21] and [24]. In the study by the EFPIA, cited above at n.22, p.64 with n.208 the significance of this judgment is incorrectly restricted to the case of price level abuses which are already forbidden anyway.

25 Case 27/76, cited above at n.11, [130]–[138] *et seq.*

prohibition was rejected as being abusive.²⁶ The Court of First Instance ("CFI") made a similar argument in the case of *Irish Sugar*.²⁷ There it deemed as abusive a discount system by the Irish market dominator aimed at restricting sugar imports from Northern Ireland. The court emphasised that the influence of the price policy of companies in one Member State on the market participants in a bordering Member State is in the nature of the common market. Any interference with this cross-border influence must thus be regarded as an obstacle to the realisation of the single market and to effective and undistorted competition. According to the CFI, if such obstacles to market integration are due to the behaviour of a company with a market dominating position, this constitutes an abuse in contravention of Art.82 EC.²⁸ The CFI took the same line in the case of *AAMS/Commission*. There it rejected measures as abusive which were aimed at limiting the import of foreign cigarettes into Italy.²⁹

These judgments show that measures by market dominating companies aimed at preventing exports of their products so that they are exposed to as little competition as possible in other national markets can be classified as abusive "per se", because they are in contradiction of the market integration intended by the EC Treaty.³⁰ This means that the refusal to supply always constitutes an abuse of a market dominating position if it is aimed at and actually causes a foreclosure of the national markets for the protection of the company's own competitive position.³¹ This is the case here due to the limitation of

the supply quantity to the domestic requirements and the thus intended and effected prevention of parallel trade. The charge of abuse made here is not the same as a general obligation on the part of market dominating companies to always adapt their production capacity to the wishes and order quantities of their customers. No such general obligation can be derived from Art.82 EC. The abusive nature of the supply restrictions in this case is based rather on the peculiarity that the quantities were deliberately reduced in such a way as to make it practically impossible for the wholesalers to export. In the application of Art.82 EC it is acknowledged that an otherwise permissible measure can become abusive "per se" where it pursues impermissible aims, particularly the partitioning of national markets.³²

2. Validity of the competition rules despite diverging price regulations in individual states

The fact that parallel trade on the pharmaceuticals markets is due mainly to price differences between the Member States resulting from divergent price regulations in the individual states does not alter the fact of an abuse due to supply restrictions by market dominating pharmaceutical companies aimed at combating parallel trade. In its parallel trade jurisprudence on Art.28 EC, the ECJ has repeatedly established that even where the imposition of price controls actually constitutes a situation which, under certain conditions, could distort competition between the Member States, this situation cannot justify an exception to the basic principle of free movement of goods.³³ Rather, distortions of competition due to differing national price regulations should, according to established practice, be eliminated by measures of the EC authorities and not by another Member State introducing measures which are irreconcilable with the rules of the Common Market.³⁴ Even if pharmaceuticals manufacturers have no extensive influence on the diverging prices, they cannot evoke their patent or brandname rights to resist the importation of a product which was circulated with their approval in

26 Case 27/76, cited above at n.11, [152]–[160]; see also Möschel in: *Immenga/Mestmäcker*, cited above at n.21, Art.86 para.181; Bellamy & Child, cited above at n.20, para.9–084.

27 Case T-228/97, *Irish Sugar/Commission* [1999] E.C.R. II-2969.

28 Case T-228/97, cited above at n.27, [185].

29 Case T-139/98, *AAMS/Commission* [2001] E.C.R. II-3413 at [94].

30 Also Dirksen, in *Commentary on German and European Antitrust Law*, (Langen/Bunte, Vol.1, 9th ed., 2001), Art.82 EC paras 128 *et seq.*; Möschel, in *Immenga/Mestmäcker*, cited above at n.19, Art.86 a. F. para.181; Schröter, in v. d. Groeben/Schwarze, cited above at n.20, Art.82 EC paras 210 *et seq.* and 253; Weiß, in *Commentary of the EU and the EC Treaty*, (Calliess/Ruffert, 2nd ed. 2002), Art.82 para.48; see also Case 226/84, cited above at n.22, [24]; Case 27/76, cited above at n.11, [152]–[160]. According to this, export restrictions are not merely forbidden as a means of reinforcing some other abusive behaviour, but forbidden *per se*. This is not invalidated by the case of *Hilti*, in which there was an impermissible tying policy as well as the abusive export prohibition, Commission Decision, *Eurofix-Bauco/Hilti* [1988] O.J. L65/19 at para.76; confirmed by the CFI in Case T-30/89, *Hilti/Commission* [1991] E.C.R. II-1439 at [16] and [96] *et seq.*; thus non-applicable EFPIA, cited above at n.22, p.64.

31 Möschel, in *Immenga/Mestmäcker*, cited above at n.21, Art.86 a. F. para.229; see also Ritter/Braun/Rawlinson, *EC Competition Law* (2nd ed., 2000), p.365; less clear, Case T-41/96, cited above at n.5, [176], where the court, however, did

not have to rule on an abuse pursuant to Art.82 EC and thus did not have to list the requirements individually.

32 See Case 226/84, cited above at n.24, [24]; Case T-65/89, *BPB Industries and British Gypsum/Commission* [1993] E.C.R. II-389 at [94]; Bellamy & Child, cited above at n.20, paras 9–69; Möschel, in *Immenga/Mestmäcker*, cited above at n.21, Art.86 para.229; Dirksen, in *Langen/Bunte*, cited above at n.30, Art. 82 EC para.125; this is misconstrued by the EFPIA, cited above at n.22, pp.60 and 63 *et seq.*

33 Cases C 267 & 268/95, *Merck/Primecrown* [1996] E.C.R. I-6285 at [47]; also Joined Cases C 427, 429 & 436/93, *Bristol-Myers Squibb* [1996] E.C.R. I-3457 at [46]; see Case 16/74, cited above at n.2, [16] *et seq.*

34 Cited above.

another Member State. Industrial property rights are, after all, not there to allow their proprietors to foreclose national markets.³⁵

Just as the individual national price regulations do not justify exceptions to the principle of the free movement of goods, nor do they allow exceptions to the EC competition rules. In particular, a market dominating pharmaceuticals company which deliberately restricts its supplies in order to prevent parallel trade, cannot claim that the market partitioning effect of this behaviour is not based on a corporate measure but on the state regulation conditions. On the contrary, disparate national price regulations serve as an incentive for the export of goods from the low-price system for import into the high-price system. The legal obligation of the wholesalers to keep a reserve for domestic requirements does not as such lead to national market foreclosure.³⁶ It only provides the regulatory background which allows the pharmaceuticals manufacturers to prevent cross-border trade with the help of deliberate supply restrictions. The argument that the prevention of parallel trade is only eliminating the competition distortions resulting from the diverging state regulations cannot be taken into consideration either within the application of Art.28 EC or within the application of Art.82 EC.³⁷ The realisation of the single market demands, namely, that even in the case of different national conditions, cross-border trade within the EU may not be restricted without a substantial justification. This is the only way that market integration can be advanced and competition between the national regulation systems be realised.³⁸ If the system competition alone is not sufficient to eliminate the regulatory frictions caused by price differences in the long-term, the corresponding regulations must be harmonised on the EC level.³⁹ Until then, however, complete compliance with the EC competition rules must be ensured in order to avoid setbacks to the

process of integration.⁴⁰ If market dominating companies were allowed to operate deliberate policies to combat parallel trade, this would not eliminate the obstacles to the free single market based on diverging national price regulations, but rather reinforce them. Market foreclosing measures—whether by companies or individual states—are thus not acceptable as a response to diverging price regulations in the Member States. This is why the ECJ has emphasised on a number of occasions that, despite state-induced price differences, parallel trade with pharmaceutical products is protected by the principle of the free movement of goods.⁴¹ Thus, the freedom granted to pharmaceutical wholesalers by the EC Treaty to exploit existing price difference for arbitrage transactions may not be undermined by supply blockades imposed by market dominating companies.⁴²

As well as in the pharmaceuticals sector, in other sectors, particularly the auto trade, there are also considerable price differences between the Member States which are based mainly on different tax rates and thus can only be influenced to a limited extent by companies. Nonetheless, neither the Commission nor the ECJ have accepted the considerable tax differences as a justification for the prevention of parallel trade by car companies.⁴³ The ECJ has also expressly ruled that the lack of harmonisation in the tax regulations does not release the car manufacturers from their obligation to observe the main rules of the single market including the prohibition on market foreclosure.⁴⁴ The same obligation has to apply for market dominating pharmaceuticals companies.

The sector specific regulation of the pharmaceuticals markets does not do anything to change the comprehensive validity of the abuse prohibition pursuant to Art.82 EC. In particular, the national price regulations do not represent a comprehensive abusive practices control. They only serve to prevent price level abuses at the expense of the health systems and not as a substitute

35 Joined Cases C 427, 429 & 436/93, cited above at n.33, [45] *et seq.*

36 EFPIA thus inapplicable, cited above at n.22, p.63.

37 Also according to the Greek Competition Commission, cited above at n.6, GRUR Int. [2002] 534 (538).

38 Thus the Commission regards parallel trade as an engine of market integration, see the Commission Communication on the single market in pharmaceuticals, November 25, COM (1998) 588 final, p.6; see also Bellamy & Child, cited above at n.20, para.1-078.

39 Thus the Commission is now considering new ways of harmonising the national regulations on drugs expenditure, see also the Communication from the Commission, July 1, 2003, *A Stronger European-based Pharmaceutical Industrie for the Benefit of the Patient: A Call for Action*, COM (2003) 383 final, pp.17 *et seq.*

40 See also Commission, Communication cited above, p.19.

41 See the verifications in n.33.

42 Similarly within the scope of Art.81 EC: Commission Decision cited above at n.18, [130] *et seq.*

43 See, e.g. Cases 209-215 & 218/78, *Landewyk Sarl/Commission* [1980] E.C.R. 3125 at [153]; Commission Decision, *Opel Nederland* [2001] O.J. L59/1 at [15] and [118]; as here also Commission Decision, cited above at n.18, [132]

44 Case T-62/98, *Volkswagen/Commission* [2000] E.C.R. II-2707 at [336]; confirmed in Case C-338/00 P [2003] I-9189 at [143] and [151]; on the prohibition of market foreclosing measures, see also Case C-70/93, *Bayerische Motorenwerke* [1995] E.C.R. I-3439 at [37].

for the general competition rules.⁴⁵ The EC⁴⁶ and Member State regulations regarding market authorisations and distribution of pharmaceutical products are in themselves not sufficient to achieve the aim of guaranteeing undistorted competition. They serve, rather, for the realisation of the single market⁴⁷ while ensuring effective health protection and an adequate supply of medicaments without preventing all abusive behaviour on the part of market dominating companies. Even in areas in which the freedoms of the companies are restricted by state imposed regulations, it is the task of the competition rules to protect the remaining competition and to prevent any reinforcement of existing single market obstacles by corporate practices.⁴⁸ The validity and scope of the prohibition on the abuse of market dominating positions are thus not relativised by the existing sector-specific regulations in the pharmaceuticals sector.

Despite the diverging price regulations in the Member States and the EC harmonisation of certain public interest obligations, the competition rules must therefore be applied in the pharmaceuticals sector just as in other economic sectors. The question as to whether the measures taken by GSK to prevent parallel trade constitute a prohibited abuse can, therefore, be answered with the aid of the criteria generally applicable within the scope of Art.82 EC. Although market dominating companies are, in principle, not denied the right to protect their own commercial interests, there is a lot to suggest in this case that, in contradiction of the opinion of the Advocate General, the supply restrictions of GSK constitute a practice which is abusive "*per se*" and not subject to any objective justification.⁴⁹ For, according to established rulings, measures aimed at the partitioning of national markets constitute particularly serious

restrictions on competition⁵⁰ which cannot be accepted⁵¹ as they contradict the single market rights guaranteed by the principle of the free movement of goods.

III. No objective justification

Even if one agrees with the premise of the Advocate General that market dominating companies generally have to be allowed to prove an objective justification of their behaviour, one must come to the conclusion in this case that the behaviour of GSK cannot be justified. The Advocate General lists three aspects which, in his opinion, represent a justification for the supply restrictions imposed by GSK. First, he assumes that, in view of the general obligation of continuous provision of the drugs, the execution of all orders would be a disproportionate burden on the company. Secondly, he assumes that the supply obligation might act as a disincentive to pharmaceutical companies to innovate. Thirdly, it is claimed that there is nothing to suggest that parallel trade would actually be of any benefit to the ultimate consumers or the Member States as primary purchasers.⁵²

The burden of explanation and proof of these assumptions lies with GSK as the party claiming a justification for supply restrictions.⁵³ Even the Advocate General assumes at first that the conditions for an objective justification have to be *demonstrated*.⁵⁴ He then strays away from this position, however, by listing a number of justifying circumstances without demanding any proof of these. As is explained below, in this case

45 Also with regard to access agreements in the telecommunications sector the Commission has made it clear that the observance of sector-specific rules regarding open network access does not exempt from compliance with the general EC competition rules, see also Commission Communication on the application of the competition rules to access agreements in the telecommunications sector [1998] O.J. C265/2, paras 11 *et seq.*, particularly para.22.

46 See, in particular, the so-called Community Code for proprietary medicinal products, Directive 2001/83 [2001] O.J. L311/67, last amended by Directive 2004/27 [2004] O.J. L136/34.

47 This aim is pursued in particular by the system of mutual recognition of national market authorisations as well as the decentralised procedure pursuant to Title III, Ch.4 (Art.27 *et seq.*) of Directive 2001/83, cited above at n.46.

48 Details on this within the scope of Art.81 EC: Engelmann, *Limitation of healthcare Costs and EC Competition Law* (2002), p.103 *et seq.*; for the significance of the protection of residual competition on highly regulated markets also Joined Cases 209-215 & 218/78, cited above at n.43, [131] *et seq.*

49 See also the Competition Commission, cited above at n.6, GRUR Int. [2002] 534, at 537 *et seq.*; expressing doubts Gassner, PharmR [2004] 57 (62).

50 See *e.g.* Case T-62/98, cited above at n.44, [336]; confirmed in Case C-338/00 P, cited above at n.44, [151].

51 In the Case *United Brands* the ECJ refused to accept objective reasons for the disputed prohibition on resale due to its market-insulating effect: Case 27/76, cited above at n.11, [152]-[160]. Also in the case *British Leyland* it categorised the prevention of re-imports as abusive *per se*, Case 226/84, cited above at n.24, [24]; also Schröter, in: v. d. Groeben/Schwarze, cited above at n.20, Art.82 EC para.253.

52 Jacobs A.G., Case C-53/03, cited above at n.6, [100], exhaustively [77]-[99].

53 In the case of *Irish Sugar* the CFI emphasised that the market dominating company as plaintiff had failed to present the necessary proof that the measures taken to protect its competitive position were based on criteria of economic efficiency and in the interests of consumers, see Case T-228/97, cited above at n.27, [189]; also in the case *AAMS/Commission* the CFI ruled that there was no proof of justification, Case T-139/98, cited above at n.29, [79] and [95]; see also Gassner, PharmR [2004] 57, at 65 *et seq.*; Möschel, in *Immenga/Mestmäcker*, cited above at n.21, Art.86 para.217 *et seq.* Misconstruing the burden of explanation and proof EFPIA, cited above at n.22, p.61.

54 Jacobs A.G., Case C-53/03, cited above at n.6, [72].

it is not possible to put forward any objective justification of the market foreclosing practices of GSK based on proven facts.

1. No disproportionate burden and no impact on the supply structure

It has already been explained above that the mere existence of diverging national price regulations does not justify any exception to the application of the prohibition on abuse.⁵⁵ Equally, the public service obligations imposed by EC and national legislators on pharmaceutical companies and wholesalers cannot be used as a justification for restrictions on parallel trade. It is true that, according to the newly second paragraph of Art.81 of Directive 2001/83,⁵⁶ both the manufacturers of pharmaceutical products as well as wholesalers are obliged within the limits of their responsibilities to ensure appropriate and continued supplies of the medicinal products sold by them. However, the claim by GSK that parallel trade prevents companies from maintaining the supply systems they are obliged to guarantee must be called into question. Particularly with regard to the import states, GSK fails to explain how parallel imports could have a negative impact on the supply structure there. But even in the export states there is no evidence of supply bottlenecks caused by parallel trade. The occurrence of supply difficulties as a result of parallel trade is, rather, actually prevented by the cited public service obligations. The actual observance of these obligations by the wholesalers in the export states can be ensured by an effective system of sanctions. Apart from this—as far as can be seen—GSK did not submit any other studies or documents showing how parallel trade had caused a negative impact on the supply structure.⁵⁷ There is, therefore, no verifiable evidence that parallel trade is preventing companies from fulfilling their supply obligations in the public interest in the export or import state. GSK had already claimed in the main proceedings before the Greek Competition Commission that supply problems had occurred on the Greek market as a result of parallel trade. According to the decision of the Competition Commission it was not possible to prove that shortages had occurred on the Greek market as a result of drugs exports. On the contrary: the Competition Commission had indications

55 See above II.2.

56 See above n.46.

57 The corresponding proof is absent in the EFPIA assessment, cited above at n.22, p.61.

that supply problems only arose after GSK stopped supplies to Greek wholesalers.⁵⁸

In so far as the Advocate General, while establishing a disproportionate burden, refers to a negative impact on the competitive position of the pharmaceutical companies caused by parallel trade in conjunction with the legal supply obligations,⁵⁹ it must be considered that a reduction in the company's profits can never in itself justify abusive, anti-competitive practices.⁶⁰ Rather, it would be necessary to prove a negative effect caused by parallel trade so that its prevention would be of benefit to consumers.⁶¹ This would be the case if it was verifiably impossible for pharmaceutical companies to organise their manufacturing and sales processes in an economically feasible manner and in conformance with the valid regulations without combating parallel trade.⁶² No such verification is possible. Thus it remains unclear how the burden on the companies manifests itself in concrete terms. There appears to be no data which proves that parallel trade in conjunction with the public interest obligations is preventing pharmaceutical companies from managing their business in an efficient and economically feasible manner. The fear that parallel trade would stop pharmaceutical companies from selling their products in so-called low-price countries and would make them reluctant to circulate new products in these countries is purely speculative. In the long history of parallel trade such fears have never been confirmed. In so far as any such trend became apparent, it would be the task of the national and European legislators to introduce the corresponding regulatory safeguards.⁶³

2. No verifiable negative impact on research and development

When the Advocate General refers to the considerable investment required for research and development ("R&D") in new, innovative drugs, it must also be noted

58 See Competition Commission, cited above at n.6, GRUR Int. [2002] 534, at 538.

59 Jacobs A.G., Case C-53/03, cited above at n.6, [86] and [100].

60 With regard to a decision on an exemption pursuant to Art.81(3) EC, also Commission Decision, cited above at n.18, [156].

61 See Case T-228/97, cited above at n.27, [189].

62 The CFI also demanded such proof in the Case T-139/98, cited above at n.29, [95].

63 The Advocate General also implicitly allows for the possibility of such a regulation by stating in a different context that the pharmaceutical companies cannot simply withdraw from the low-price countries due to the public interest obligations imposed on them: Jacobs A.G., Case C-53/03, cited above at n.6, [86].

that there is no evidence of any connection between parallel trade and GSK's R&D budget. As the Greek Competition Commission established, GSK was unable to present any data to prove that R&D funding was reduced as a result of parallel exports from Greece.⁶⁴ Even within the proceedings before the ECJ no such data appear to have been submitted. In particular, it should be noted that a possible impact of parallel trade on the profits of a company is not automatically equivalent to a negative effect on the R&D budget. As the Commission set out in more detail in a decision regarding Glaxo Wellcome in Spain, a company can react to a decline in profits by reducing other cost-intensive items.⁶⁵ Overall, the Commission was unable to establish any causal relationship between parallel trade and R&D expenditure.⁶⁶ The lack of any pertinent data is also apparent in the result formulated by the Advocate General in which he assumes that an obligation to supply *might* harm the incentive for a pharmaceutical company to engage in innovative activity.⁶⁷ According to the relevant rulings,⁶⁸ however, such an unprovable possibility alone cannot serve as a verified objective justification for abusive practices.

Even if one assumed that profit losses due to parallel trade really did have a negative impact on the R&D activities of companies, market foreclosure measures on the part of pharmaceutical manufacturers would not be an appropriate reaction to this. Although the reduction of R&D expenditure is not politically desirable, it is not the same as the inefficiency of the whole manufacturing process. Reduced R&D investment can thus not be used as a justification for market foreclosure. It should rather be a matter for the national and European decision-makers to change the underlying conditions and create stronger regulatory incentives for R&D. In contrast, it is irreconcilable with the basic principle of the common market if pharmaceutical companies use their R&D budget as an excuse to prevent other market participants from being involved in cross-border trade.⁶⁹ To allow this would be to unjustifiably undermine the free movement of goods protected by Art.28 EC.

64 Competition Commission, cited above at n.6, GRUR Int. [2002] 534 at 538.

65 Commission Decision, cited above at n.18, [157].

66 Commission Decision, cited above at n.18, [158]–[160].

67 Jacobs A.G., Case C-53/03, cited above at n.6, [100].

68 See, in particular, Case T-228/97, cited above at n.27, [189]; as well as Case T-139/98, cited above at n.29, [79] and [95].

69 See also Schröter, in: v. d. Groeben/Schwarze, cited above at n.20, Art.82 EC para.253, who regards the erection of barriers to cross-border trading between independent traders in principle as a contravention against the competition rules of the Treaty.

3. Benefits of parallel trade for consumers and Member State health systems

Finally, the Advocate General argues that parallel trade is of no benefit either to the ultimate consumers of pharmaceutical products, particularly the holders of health insurance, or to the Member States health systems as their main purchasers, so that the prevention of parallel trade has no disadvantages. This line of argument has to be regarded critically to the extent that any justification for parallel trade restrictions depends not on the putative benefits of the *parallel trade*, but on the benefits of the *restriction measure*. In addition to this, the question as to the social value of parallel trade is not relevant because it calls into question the system of free movement of goods and thus the common market itself. The protection of the free movement of goods does not depend on the degree of social value of the activity concerned, and restrictions are only permitted if, taking into account the basic principle of proportionality, they serve recognised public interest considerations and do not lead to market foreclosure.⁷⁰ Article 82 EC is meant to flank this common market system. This is expressed in such a way that deliberate market foreclosure measures are forbidden as "hard-core abuses"—in contrast to other trade restrictions pursuant to Art.82(2)(b) EC—pursuant to the general clause of Art.82(1) EC, even without consumers being prejudiced by the respective market foreclosing measure.⁷¹ Equally, for a justification of corporate practices to restrict parallel trade it should be of no consequence which advantages the consumer has from parallel trade.

Furthermore, the absence of advantages of parallel trade to consumers and health systems is not actually verified. On the contrary, a study by the York Health Economics Consortium ("YHEC") in May 2003 came to the conclusion that parallel trade could result in considerable direct and indirect savings.⁷² The study was carried out for Great Britain, Germany, the Netherlands, Sweden and Denmark—the five EU countries where most parallel imports take place.⁷³ According to the study, in 2002 the cited countries saved a total of €635 million, not counting the indirect savings made

70 This system clearly arises from Art.30(2) EC. According to established rulings a hidden restriction of trade forbidden by this is constituted in the case of market foreclosure, see Case C-143/00, cited above at n.23, [31] *et seq.*

71 See Schröter, in: v. d. Groeben/Schwarze, cited above at n.20, Art.82 EC para.253; for the application of the general clause where the consumer is not prejudiced see also Möschel, in: Immenga/Mestmäcker, cited above at n.21, Art.86 a. F. para.216.

72 West/Mahon, *Benefits to Payers and Patients from Parallel Trade*, study by the YHEC, commissioned by the European Association of Euro-Pharmaceutical Companies, May 2003.

73 West/Mahon, cited above, p.5.

through price competition. According to the YHEC the direct savings achieved passed mainly to the respective health insurance systems, but also to patients in so far as there is co-payment involved.⁷⁴ For example, in Germany in the year 2002 alone over €10 million was saved on oral contraceptives.⁷⁵ As these costs are borne mainly by the consumers themselves, they benefited directly from the savings.⁷⁶

The basic conditions described by the advocate general in some states do not contradict the findings of the YHEC study. On the contrary, if the claims made by the Advocate General in his opinion are brought to their logical conclusion, they also indicate that parallel trade has the potential for savings in the national health systems. The Advocate General claims, for example, that some Member States have passed reimbursement regulations in order to recover a portion of the profit which the pharmacists in particular have gained as a result of parallel trade. This shows that parallel trade has led to savings for the health system. In general, the regulatory conditions in all of the main importing states are such that the price advantages generated by parallel trade are passed on to the national health insurance system and thus indirectly to the insured persons.⁷⁷ In its Communication on the single market for pharmaceutical products, the Commission also emphasises the possibility of introducing such regulatory measures for the Member States. To this extent, the Advocate General quotes the Commission Communication incompletely by only emphasising the passage which says that parallel trade can lead to inefficiency if the profit remains with the parallel traders.⁷⁸ Directly after this, the Commission states: in so far as the market structure does not allow for the gains made through parallel trade to be passed on to the consumer and the tax payer, this can generally be ensured by the introduction of appropriate national measures.⁷⁹ All of the main importing Member States have introduced such measures.

The healthcare systems in Denmark, Germany and Sweden make savings directly from the lower costs of

the parallel imported products compared to the pharmaceutical products produced domestically. This is because the respective healthcare systems reimburse the costs of drugs only to the level of the actual pharmacy retail prices—in some cases subject to a certain maximum amount.⁸⁰ This means that lower drugs prices as a result of parallel trade are directly reflected in the expenditure of the healthcare systems.⁸¹ As the percentage pharmacist margin⁸² in the states mentioned means that there is no financial incentive to pharmacists to increase their sale of parallel imported drugs, the Member States have provided other mechanisms to promote the sale of low-cost parallel imports. In Denmark, for example, the pharmacists are legally obliged to inform patients about any cheaper substitute preparations available.⁸³ In Germany, pharmacists are obliged pursuant to s.129(1) SGB V, to sell low-cost, imported drugs. Pursuant to the amendment which became effective in January 2004, this obligation only applies to imported drugs whose retail price is at least 15 per cent or €15 lower than the German reference price. Furthermore, the framework agreement on drugs provision obliges pharmacists to achieve an import quota of 5 per cent which must include a 10 per cent so-called profitability reserve. These regulations are clearly aimed at achieving the maximum possible savings for the statutory health insurance system in Germany by low-cost parallel imports. Since October 2002 pharmacists in Sweden are also legally obliged to sell the lowest-cost parallel imported substitute preparation.⁸⁴

In the Netherlands and in Great Britain, parallel trade is promoted not by legal obligations, but by economic incentives for the pharmacists. In the Netherlands, for example, similar to the situation in Germany, there is a reimbursement upper limit in the form of a reference price to limit the drugs expenditure of the healthcare system. When pharmacists sell imported drugs whose price is below the reference price, two-thirds of this price difference go to the health insurance company and one-third is retained by the pharmacist. There is also a

74 West/Mahon, p.67; details regarding the individual states, pp.7–66.

75 West/Mahon, p.51.

76 For the possible substantial savings for the contraceptive pill see also the press release by the Scientific Institute of the AOK (WIdO), October 10, 2002, Imported drugs can save €450 million per year.

77 See also the study by the LSE which, however, contrary to the YHEC study—estimates the savings for the health systems as less than the profits of the parallel traders, see Kanavos/Costa-i-Font/Merkur/Gemmill, *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis*, (January 2004), p.85.

78 Jacobs A.G., Case C-53/03, cited above at n.6, [98].

79 Commission Communication, cited above at n.38, p.6.

80 In Germany the reference prices pursuant to s.35 SGB V form the reimbursement upper limit for many drugs.

81 See West/Mahon, cited above at n.72, pp.8, 24 *et seq.* and 48; also Kanavos *et al.*, cited above at n.77, p.86.

82 Since the GKV modernisation bill became effective on January 1, 2004, this only applies to a limited extent in Germany, as a fixed supplement amounting to €8.10 is paid in addition to the percentage pharmacy supplement of 3 per cent, see §3(1) of the *Arzneimittelpreisverordnung* (drugs price regulations).

83 This obligation applies as of a fixed minimum price difference between the domestic original preparation and the substitute preparation, see West/Mahon, cited above at n.72, p.7 *et seq.*; see also Commission Decision, cited above at n.18, [52].

84 West/Mahon, cited above at n.72, p.23 *et seq.* Sweden is a special case in that the pharmacies are not independent but part of the state monopoly “*Apoteket*”.

claw back system under which the discounts granted to the pharmacists by the wholesalers as well as any other gains are supposed to be clawed back by the healthcare system. The pharmacists have to repay a certain percentage lump sum of the retail price to the healthcare system. This system gives the pharmacists an added incentive to increase the sale of low-cost drugs as their profits are affected less by the claw backs in the case of cheaper drugs.⁸⁵ The Dutch healthcare system profits from this, on the one hand, by the passing on of two-thirds of the price advantage and, on the other hand, through the clawback system. In Great Britain the National Health Service reimburses the pharmacists for the drugs sold regardless of the pharmacists' purchasing price in accordance with a fixed list price. Thus it is an advantage for pharmacists to purchase drugs cheaply in the form of parallel imports. In order to pass on the gains made by the pharmacists through parallel trade to the NHS there is a claw back system similar to that operating in the Netherlands. The pharmacists deduct a certain percentage from the list price for the NHS. The level of the deduction depends on the level of savings which all British pharmacists achieve per year on the basis of parallel trade.⁸⁶ This means that a large part of the profits generated by parallel trade directly benefit the NHS. If the pharmacists operate a clever purchasing policy, then they can retain part of the profits.

All of this shows that the Advocate General has given only an incomplete representation of the effects of parallel trade in the importing states. In particular, the conclusion that parallel trade can have a negative effect on the interests of the importing states or on their health systems is questionable. Rather, the regulations in the Member States as set out above result in a situation where there is a substantial interest in the savings which can be achieved through parallel trade.⁸⁷ This means that any measures to prevent parallel trade will have a negative impact on the interests of the consumers (insured persons) and the healthcare systems in the importing states as they will be prevented from taking advantage of the direct and indirect savings which can be achieved through parallel trade.⁸⁸

85 For more on the Dutch system see West/Mahon, cited above at n.72, p.38 *et seq.*; Kanavos *et al.*, cited above at n.77, p.64 *et seq.* and 70.

86 West/Mahon, cited above at n.72, p.60; Commission Decision, cited above at n.18, [49].

87 Thus the argument that parallel trade undermines the regulations of the Member States within their healthcare systems does not apply, EFPIA is thus also incorrect, see above at n.22, p.60 *et seq.*

88 This does not contradict the fact that the parallel traders themselves make substantial profits, as the LSE study emphasises, see also Kanavos *et al.*, cited above at n.77, p.135. Regardless of the fact that the basic data and the methodology used by

IV. Conclusions

In conclusion, everything points to the fact that, by restricting supplies to Greek wholesalers in order to prevent parallel trade, GSK has abused its market dominating position as established by the Greek Competition Commission. In the interpretation of the prohibition on abuse in light of the aim of the Treaty to promote market integration, the undisputed intention of market foreclosure in itself constitutes a contravention of Art.82 EC. To this extent, the prohibition on abuse flanks the principle of the free movement of goods pursuant to Art.28 EC. The ECJ has confirmed on a number of occasions that market dominating companies may not behave in such a way as to re-erect barriers to cross-border trade which were removed by the principle of the free movement of goods. This obligation also applies to market dominating companies despite diverging price regulations in the Member States. Just as the price differences induced by regulations do not, in accordance with established legal practice, justify any exceptions to the free movement of goods, they also allow no deviation from the EC competition rules. For this reason, the prevention of parallel trade by companies must be regarded as a particularly serious contravention against the prohibition on abuse which is unjustifiable *per se*. Even if one assumes that there may be a justification in principle, no justifying circumstances have been brought forward or verified in this case. The assumptions made by the Advocate General do not in themselves meet the requirements for the verification of objective justification demands which is the task of the market dominating companies. No data has been presented to prove either a negative impact on the supply structure or on research and development. Also, any empirical studies carried out up to now suggest that an important part of the gains generated by parallel trade is being passed on to the healthcare systems of the respective importing countries due to the corresponding regulations in those countries.

In summary, the criticism must be expressed that the Advocate General's assumption of a possibility of justifying final market foreclosing measures calls into question the integrative intention of the EC Treaty and thus

the authors demand critical analysis (see West/Mahon, *A Commentary on the LSE Report The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis* (March 2004), the savings potential for the healthcare systems still apply when the parallel traders make equally high or in some cases even higher profits.

the very principle of the free movement of goods. This applies in particular when, for the purpose of justification, reference is made to the differing price regulations in the Member States and the alleged absence of any benefits from parallel trade. The aim of market integration cannot be reconciled with allowing market dominating companies to actually reinforce distortions of competition and barriers to the single market caused by the existing regulations. Parallel traders involved in cross-border trade which is protected by the Treaty cannot be blamed for the effects of diverging Member State regulations. Rather, it is for the national and European legislators to provide the basic conditions for

undistorted competition in the single market by adapting the regulations accordingly. It is to be hoped that in its ruling the ECJ will deviate from the opinion of the Advocate General and support the complementary interaction of the principle of the free movement of goods and the prohibition on abuse of a market dominating position taking into account the meaning of the single market. This is all the more important given that, as well as the pharmaceuticals sector, the ruling will probably have a major impact on other economic sectors which are also subject to price differences between the Member States as a result of national regulations.