Editors
Sir David Edward
Jacquelyn MacLennan
Assimakis Komninos

Ian S. Forrester QC LL.D.

A Scot without Borders
Liber Amicorum - Volume II

Peter Alexiadis, Jean-Yves Art, Carl Baudenbacher, Jean-François Bellis, Kent Bernard, Helmut Brokelmann, Eleanor M. Fox, Ayşe Gizem Yaşar, Rosa Greaves, Ayşe Güner, Gönenç Gürkaynak, Barry E. Hawk, Nicholas Khan, James Killick, Assimakis P. Komninos, Santiago Martínez Lage, Valérie Meunier, Jorge Padilla, Mark Powell, Francesco Setti, Luís Silva Morais, Jacques Steenbergen, Pablo Trevisán, Mathieu Vancaillie, James S. Venit, Denis Waelbroeck, Karen Williams.

GO TO TABLE OF CONTENTS

Concurrences
Review, Bulletin, Books, Conferences

IAN S. FORRESTER QC LL.D.

A Scot without Borders

Liber Amicorum - Volume II

Editors

Sir David Edward

Jacquelyn MacLennan

Assimakis Komninos

GO TO TABLE OF CONTENTS

60 Broad Street, Suite 3502, NY 10004
www.concurrences.com
contact@concurrences.com
Printed in United Kingdom
First Printing, 2015
ISBN 978-1-939007-28-5

Cover and book design by Yves Buliard, www.yvesbuliard.fr

GO TO TABLE OF CONTENTS

Contributors

Peter Alexiadis
Gibson Dunn

Jean-Yves Art
Microsoft

Carl Baudenbacher
EFTA Court

Jean-François Bellis
Van Bael & Bellis

Kent Bernard
Fordham University School of Law

Helmut Brokelmann
Martínez Lage, Allendesalazar & Brokelmann

Eleanor M. Fox
New York University School of Law

Ayşe Gizem Yaşar
ELIG

Rosa Greaves
University of Glasgow

Ayşe Güner
ELIG

Gönenç Gürkaynak
ELIG

Barry E. Hawk
Fordham University School of Law

Nicholas Khan
European Commission

James Killick
White & Case

Assimakis P. Komninos
White & Case

Santiago Martínez-Lage
Martínez Lage, Allendesalazar & Brokelmann

Valerie Meunier
Compass Lexecon

Jorge Padilla
Compass Lexecon

Mark Powell
White & Case

Francesco Setti
Avvocati Associati Franzosi Dal Negro Setti

Luís Silva Morais
Luís Silva Morais Sérgio Gonçalves do Cabo & Associados

Jacques Steenbergen
Belgian Competition Authority

Pablo Trevisán
Estudio Trevisán Abogados

Mathieu Vancaillie
Ashurst

James S. Venit
Skadden Arps

Denis Waelbroeck
Ashurst

Karen Williams
European Commission

▶ GO TO TABLE OF CONTENTS

Table of Contents

Part IV - Competition Law

▶ GO TO TABLE OF CONTENTS

▶ GO TO TABLE OF CONTENTS

Part IV
Competition Law

Parallel trade after the GlaxoSmithKline judgments

Santiago Martínez Lage and Helmut Brokelmann

I. The problem of parallel trade in the pharmaceutical sector

Unlike most competition regimes outside the EU, European competition law not only pursues the classical objective of enhancing consumer welfare, but also the objective of creating an internal market among the Member States of the EU (which, eventually, should also promote consumer welfare). This is why vertical restrictions of competition have traditionally been treated differently in EU competition law, since they are liable to compartmentalize the internal market along national boundaries, e.g., through the grant of absolute territorial protection, thus reversing the market integration sought by Article 3(3) of the Treaty on European Union, Article 3(1)(b) of the Treaty on the Functioning of the European Union (TFEU), its 27th Protocol and their predecessors in the EC Treaty (Articles 2 and 3(1)(g) EC).

A specific concern of the European authorities in their competition policy concerning vertical restraints has been the promotion of parallel trade. Parallel trade is so important for the EU's single market imperative because it fosters the interpenetration of national territories and acts as a corrective to excessive price differentials between Member States. One could therefore say that parallel trade has been, and still is, a 'sacred cow' of EU competition policy, all the more so in the Euro area of comparable prices and online cross-border shopping.

▶ GO TO TABLE OF CONTENTS

While these policy aims are, as a matter of principle, completely legitimate to pursue in any industrial sector (e.g., tennis balls[1]), in the pharmaceutical sector, parallel trade has raised specific issues that put the European Commission's policy into question. In the pharmaceutical sector, parallel trade stems from structural differences in the prices of medicines as a result of different national legislations which fix the prices of these products to a greater or lesser extent. The origin for parallel trade in this sector is therefore not a policy of price discrimination applied by manufacturers between different territories but State intervention in the determination of the price, which the public health systems of the different Member States are prepared to reimburse to pharmaceutical companies.

This fact allows questioning the legitimacy of parallel trade in this specific sector, and explains why pharmaceutical companies have since the seventies tried to oppose parallel imports of their products from other Member States in which the intervened price of the same product is much lower than in the country of destination. While the benefits of parallel trade in pharmaceuticals for consumers in the country of import are limited because exporters usually pocket the advantage in terms of prices which parallel trade may entail as a windfall profit, parallel exports lead to shortages of supply in the country of export and reduce the ability of pharmaceutical companies to invest in R&D.

In our contribution to this Liber Amicorum for our learned colleague and friend Ian Forrester, we will analyze the decisions adopted in the aftermath of that case by the Spanish competition authority, their reversal by the Spanish High Court (*Audiencia Nacional*) and Supreme Court (*Tribunal Supremo*), and the way forward as regards the yet unresolved issue of the compatibility of dual pricing schemes in the pharmaceutical sector with Article 101 TFEU.

II. Parallel trade and the free movement of goods

The first route tested by pharmaceutical companies to oppose parallel imports of their products was the Treaty's provisions on the free movement of goods. The companies attempted to oppose such imports on the basis that their intellectual property rights (patents or trademarks) had not been exhausted by marketing the same product in a lower-priced Member State in which there was also no patent protection.[2]

The European Court of Justice (ECJ), however, refused to limit the fundamental freedom of free movement of goods (Art. 34 TFEU) in such circumstances and held that the

---

* Martinez Lage, Allendesalazar & Brokelmann, Madrid. The authors were co-counsel to GSK in the proceedings before the European Commission and both EU Courts.

1 See Judgment of 27 October 1994, *Dunlop Slazenger International Ltd/Commission*, T-35/92, EU:T:1994:259 and Commission Decision 94/987/EC of 21 December 1994 relating to a proceeding pursuant to Article 85 of the EC Treaty (IV/32.948 - IV/34.590 *Tretorn and others*), OJ L 378/45 of 31.12.1994.

2 Judgment in *Merck/Stephar,* 187/80, EU:C:1981:180.

▶ GO TO TABLE OF CONTENTS

exhaustion doctrine applied fully, irrespective of any price intervention or differing patent protection regimes.[3] In the *Centrafarm/Sterling Drug* case, Sterling Drug had tried to argue that price differences resulting from State price control measures should permit the holder of a patent for the product in question to oppose parallel imports, although such opposition would normally be contrary to the exhaustion of rights principle (i.e., the 'exhaustion' of the right to invoke national intellectual property legislation in order to prevent parallel imports if the product in question has been put onto the market in the Member State of exportation either by the rightholder itself or with its consent). The Court, however, rejected the parties' arguments to allow the patent holder to oppose parallel imports contrary to the exhaustion of rights principle, thus refusing to acknowledge that the legislation of the country of origin did not allow the IP rightholder to realize the full economic value of its right in that country.

This case law was again confirmed in the 1996 *Merck/Primecrown* judgment[4] in which the Court declared that 'although the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States, that circumstance cannot justify a derogation from the principle of free movement of goods. It is well settled that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules on free movement of goods' (para. 47).

Thus, the Court does not consider the fact of a Member State fixing the price of certain products to be sufficient to justify a restriction on imports under the terms of Article 36 (that is, the undertaking harmed by such imports cannot oppose those imports by invoking a national intellectual property right recognized under Article 36 as an exception to the free movement of goods). Pharmaceutical companies cannot justify the application of national trademark or patent laws to oppose parallel imports of their products on the basis of Article 36 TFEU.

III. Parallel trade and the competition rules: the EU proceedings in GSK Spain

After it had become clear in the *Merck/Primecrown* judgment of 1996 that the free movement of goods provisions did not provide a solution to the problem of parallel trade, GlaxoSmithKline (GSK) decided to pursue a new route by justifying restrictions of parallel trade in the context of the competition rules. The Court's above-mentioned *Centrafarm/Sterling Drug* ruling provided the basis for this novel approach. In this judgment the Court held that: 'This question requires the Court to state, in substance,

3 Judgment in *Centrafarm/Sterling Drug*, 15/74, EU:C:1974:114 and Judgment in *Merck/Stephar,* EU:C:1981:180.

4 Judgment in *Merck/Primecrown, joines cases* C-267/95 and C-268/95, EU:C:1996:468.

▶ GO TO TABLE OF CONTENTS

whether the patentee can, notwithstanding the answer to the first question [which dealt with the free movement of goods provisions], prevent importation of the protected product, given the existence of price differences resulting from governmental measures adopted in the exporting country with a view to controlling the price of that product. It is part of the Community authorities' task to eliminate factors likely to distort competition between Member States, in particular by the harmonisation of national measures for the control of prices and by the prohibition of aids which are incompatible with the common market, *in addition to the exercise of their powers in the field of competition*.'

1. The Commission's GSK decision

Following this indication from the Court,[5] in 1998, GSK Spain (then still Glaxo Wellcome) notified to the European Commission new sales conditions for its pharmaceutical products in Spain. Clause 4 provided for a system of differentiated prices: while the price set by the Spanish health authorities would apply to medicines funded by the National Health System and dispensed in the Spanish territory under the applicable Pharmaceutical Act,[6] GSK would freely set a different (higher) price for any other medicine, in particular those to be exported. GSK never disputed that this clause was adopted for the purpose of limiting parallel exports of its products from Spain to other Member States. Nonetheless, in its notification, GSK argued that the clause did not restrict competition or, alternatively, deserved an exemption under the then Article 81(3) EC (currently Article 101(3) TFEU).

In a decision adopted in 2001,[7] the Commission eventually rejected GSK's request for negative clearance or individual exemption arguing that GSK's sales conditions amounted to a dual pricing scheme and to an export ban that restricted competition by 'object' and therefore did not qualify for an exemption under the third paragraph of Article 101.

2. The GSK judgment of the CFI

GSK appealed and the then Court of First Instance (CFI, today the General Court) in its ruling of 27 September 2006[8] partially annulled the Commission's decision insofar as it denied the requested individual exemption without sufficient analysis. On appeal, the European Court of Justice (ECJ, today Court of Justice) confirmed the CFI's judgment,[9] although the ECJ dissented with the lower court on the issue of whether a limitation of parallel trade restricted competition 'by object', as will be explained below.

---

5 The indication was taken up by Martínez Lage, S. in 'State price control and EC competition law', in *Fordham International Antitrust Law & Policy 1995*, pp. 161-175.

6 Art. 100 of Act 25/1990, of 20 December.

7 Commission Decision of 8 May 2001 relating to a proceeding pursuant to Article 81 of the EC Treaty Cases: IV/36.957/F3 Glaxo Wellcome (notification), IV/36.997/F3 Aseprofar and Fedifar (complaint), IV/37.121/F3 Spain Pharma (complaint), IV/37.138/F3 BAI (complaint), IV/37.380/F3 EAEPC (complaint) (notified under document number C (2001) 1202). OJ L 302, 17.11.2001, p. 1-43.

8 Judgment of 27 September 2006, *GlaxoSmithKline Services v. Commission*, T-168/01, EU:T:2006:265.

9 Judgment in *GlaxoSmithKline Services v Commission*, joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, EU:C:2009:610.

GO TO TABLE OF CONTENTS

The CFI not only annulled the Commission's rejection of the individual exemption sought by GSK but also disagreed with the Commission as to whether the sales conditions restricted competition by 'object' within the meaning of Article 101(1) of the Treaty. The Court held that it was necessary to take into account the specific legal and economic context of the pharmaceutical sector, in which the coexistence of different national legislations distorted competition. The Court confirmed that 'the price of medicines reimbursed by the national health insurance schemes is not determined as a result of a competitive process throughout the Community but is directly fixed following an administrative procedure in most Member States and indirectly controlled by the other Member States' (para. 125). Hence, 'the differences between the applicable national provisions are a structural cause of the existence of significant price differentials between Member States' (para.127) and 'those price differentials are themselves the cause of parallel trade in medicines in the Community' (para. 129).

Thus, the Court concluded that 'the 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 sports 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.' (paras. 133/134).

Consequently, the Court rejected that GSK's undisputed intention to limit parallel trade with its new sales conditions restricted competition by object, since it could not be taken for granted that parallel trade tends to reduce the prices set by the public authorities and thus to increase the welfare of final consumers.

In spite of disagreeing with the Commission on the existence of a restriction by object, the CFI nevertheless upheld the Commission's finding that the sales conditions restricted competition within the meaning of Article 101 (1) TFEU because of their anti-competitive effect. Although the CFI declared that an agreement limiting parallel trade does not necessarily restrict competition, it could do so if parallel trade contributes to price competition. In the case at hand GSK's sales conditions barely had an appreciable effect on competition because intrabrand competition between exporting wholesalers and distributors in the country of destination was 'limited' and pressure on prices resulting from parallel trade was 'marginal' given that parallel traders would not pass the price differences on to consumers in those countries. Nevertheless, the Court understood that Clause 4 of GSK's sales conditions could contribute to reinforcing pre-existing price rigidity, affecting, by network effect, a significant number of products and national markets, and therefore concluded that it had the effect of restricting competition.

▶ GO TO TABLE OF CONTENTS

3. The ECJ's judgment on appeal

On appeal, the ECJ disagreed with the CFI's conclusion that the sales conditions did not restrict competition by 'object'. Although the higher Court acknowledged that it was necessary to take into account the legal and economic context to assess whether an agreement aimed at restricting parallel trade had as its object to restrict competition, it rejected the CFI's conclusion that an agreement aimed at limiting parallel trade restricted competition by object only if it may be presumed to deprive final consumers of the advantages of effective competition in terms of supply or price. According to the ECJ, this conclusion is not supported either by the wording of Article 101 or the case law, since Article 101 protects not only interests of competitors or consumers, but also the structure of the market and, in so doing, competition as such.

The ECJ's discrepancy with the CFI is surprising for three reasons. First, because the ECJ actually did not analyze the legal and economic context, after declaring that such an analysis was necessary. Second, because in our view there should be no contradiction between the analysis of whether an agreement restricts 'competition' and the analysis of whether an agreement harms consumers. Article 101 protects the structure of the market since it presumes that the competitive functioning of the market generates benefits for consumers.

Third, because the ECJ's finding of a per se infringement arguably contradicts its *GSK Greece* judgment[10] on the compatibility of limitations of parallel trade with Article 102 TFEU. In that preliminary ruling, the Court held that restrictions of parallel trade resulting from a so-called supply quota system (by which the manufacturer unilaterally –and thus without infringing Article 101 TFEU because there is no 'agreement'[11]— limits the amounts supplied to wholesalers to the needs of the national market) do not per se constitute an abuse since even a dominant manufacturer is entitled to protect its commercial interests. Thus, if the amounts requested by wholesalers are out of all proportion to those previously sold by the same wholesalers to meet the needs of the national market, a dominant company may limit the amounts it supplies to such wholesalers without infringing Article 102 TFEU. In other words, the refusal to meet orders that are out of the ordinary because they are disproportionate as compared to the quantities previously sold by wholesalers to meet the needs of the domestic market do not infringe Article 102 TFEU.

In our view, the conclusion to be drawn from the *GSK Greece* judgment is that, if a limitation of parallel trade by a dominant undertaking does not per se constitute an abuse of a dominant position pursuant to Article 102 TFEU, it should also not constitute a restriction 'by object' under Article 101 TFEU, contrary to what the Court held in *GSK Spain*.

---

10 Judgment in *Sot. Lélos kai Sia*, joined cases C-468/06 to C-478/06, EU:C:2008:504.

11 Judgment of 26 October 2000, *Bayer* v *Commission*, T-41/96, EU:T:2000:242 and Judgment in *BAI and Bayer v Commission,* joined cases C-2/01 P and C-3/01 P, EU:C:2004:2.

▶ GO TO TABLE OF CONTENTS

4. The aftermath of the GSK judgments in the Commission's proceedings

In upholding the operative part of the CFI's judgment (albeit overturning its reasoning as regards the existence of a restriction by 'object'), the ECJ confirmed the annulment of Article 2 of the Commission's Decision, which had denied the individual exemption under the former Article 81(3) EC sought by GSK. For the purposes of complying with its judgments, the CFI had declared that 'To that end, although the notification procedure provided for in Regulation No 17 no longer exists under Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ 2003 L 1, p. 1), it falls upon the Commission, in the light of the partial annulment of the Decision and the retroactive effect thereof, to rule on the request for exemption presented by GSK by reference to the date of that request (see, to that effect, Judgment of 2 May 2006, O2 (Germany) v Commission, T-328/03, EU:T:2006:116, paragraphs 47 and 48), in so far as that request remains before it.'

However, as the Commission reports in its second *Glaxo Wellcome* Decision of 27 May 2014,[12] on 26 January 2010 GSK formally withdrew its application (of 6 March 1998) for an individual exemption under Article 101(3) TFEU, so that the Commission has never taken a new decision, in light of the judgments of both Courts, on the fulfilment of the four requirements of Article 101(3) TFEU by GSK's dual pricing scheme.

This 2014 Decision rejects the claim of the European Association of Euro-Pharmaceutical Companies (EAEPC) that the Commission was still obliged to adopt a decision on GSK's pricing scheme, against which the EAEPC had filed a complaint back in 1999. The Decision eventually rejected the complaint on grounds of lack of sufficient EU interest. According to the Commission, the EAEPC in reality did not seek an assessment of GSK's dual pricing scheme of 1998 (which GSK had suspended in 1998 and has since then not reinstated in Spain[13]) 'but rather the opening of a general investigation into parallel trade in the pharmaceutical sector in Spain which would go well beyond the scope of its Complaint.' The Decision rejects the EAEPC's argument that there is a 'causal link' between current pricing practices by other pharmaceutical companies in the Spanish market and the Commission's lack of a definitive response to the legality of GSK's 1998 scheme.

In this regard it should be noted that the Commission opened another case file in January 2012 (AT.39973, *Pricing schemes for distribution of medicines in Spain*) to investigate current parallel trade and dual pricing issues in Spain more generally, 'including pricing practices implemented by companies other than GSK.'[14] The Decision

12 Adopted under the original case number AT.36957.

13 Para. 10 of the Decision.

14 Para. 11 of the Decision.

▶ GO TO TABLE OF CONTENTS

also makes reference to two cases decided by the Spanish competition authority and the ensuing judicial appeals, to which we will refer below.

The Decision also denies that the Commission's rejections of various complaints brought against Pfizer's dual pricing scheme in Spain were based on an analysis of that scheme according to the policy set in the GSK case, since those complaints were also rejected on the basis of a lack of EU interest.

Finally, the Commission's Decision also argues that national competition authorities (and national courts) are perfectly suited to adopt decisions concerning Article 101(3) TFEU.

The Commission's 2014 Decision has been appealed to the General Court by the EAEPC[15] and it seems that it will be difficult for the GC to quash the Commission's refusal to further investigate GSK's 1998 sales conditions for lack of EU interest, since the scheme ceased to be applied a long time ago and similar schemes adopted subsequently have been analyzed by the Spanish competition authority and the Spanish courts.

IV. The aftermath in Spain

While the European Commission's policy priorities in the pharmaceutical sector switched from parallel trade to patent-related issues, particularly during the period between the CFI's and ECJ's judgments in the *GSK Spain* case, parallel traders continued to bring complaints before national competition authorities and national courts.

In Spain, these complaints gave rise to a number of decisions by the National Competition Commission (CNC), all of which rejected the claims of parallel traders. Although there have been further decisions,[16] the CNC's policy was framed in two decisions —*Spain Pharma/Pfizer*[17] and *EAEPC/Laboratorios farmacéuticos*[18]— regarding so-called 'free pricing' systems introduced by various manufacturers after the entry into force of the new Pharmaceutical Act in 2006.[19] The new pricing schemes were introduced on the background of Article 90 of the Pharmaceutical Act, which reserves the application of the regulated prices fixed by the Spanish authorities to products that are financed with public funds and dispensed in Spain. Thus, the essential argument put forward was that there was no 'dual' pricing, since manufacturers only fixed one

15 EAEPC/Commission, Case T-574/14, OJ C 409/47, of 17.11.2014.

16 For a more detailed analysis of the CNC's practice see Brokelmann, H., 'Parallel Trade after the GSK Spain Judgments', in *Reviewing Vertical Restraints in Europe* (Bellis, J.-F./Beneyto, J.M., eds., 2011), pp. 161-177.

17 Decision of the CNC of 21 May 2009 in case 2623/05 *Spain Pharma*.

18 Decision of the CNC of 14 September 2009 in case S/0017/07l; *EAEPC vs. Laboratorios Farmacéuticos*,

19 Act 29/2006, of 26 July 2006, on Guarantees and Rational Use of Pharmaceutical and Sanitary Products, Official State Gazette number 178 of 27.07.2006.

GO TO TABLE OF CONTENTS

price (for medicines not dispensed in Spain), the other price for pharmaceuticals publicly financed and dispensed in Spain being fixed by the health authorities.

1. The Spain pharma case

The Spain Pharma case is a good example of the decreasing interest of the European Commission in parallel trade cases in the aftermath of the *GSK Spain* case.

The Spanish wholesaler Spain Pharma lodged a complaint before the European Commission in relation to an alleged agreement between Pfizer and the association of wholesalers COFARES, whereby Pfizer would ensure supplies to the members of the association subject to the latter undertaking not to export.

The European Commission informed the CNC of the complaint, indicated that in its opinion the CNC was the authority best placed to deal with it, and finally rejected Spain Pharma's complaint for lack of Community interest.[20] The CNC found no evidence of the alleged agreement between Pfizer and COFARES.

In the same decision, the CNC also rejected Spain Pharma's complaint against the agreements entered into by Pfizer and its wholesalers, which according to Spain Pharma established a 'dual pricing' system. Pursuant to these so-called free pricing schemes, the manufacturer establishes a free price which is replaced by the intervened price if the product in question is financed by the State and the wholesaler proves to the manufacturer that it has been dispensed in Spain.

The CNC found that these agreements were covered by the then applicable Vertical Block Exemption Regulation.[21] Moreover, the CNC held that these agreements did not establish a 'dual pricing' system. According to the CNC, the application of a 'free price' by Pfizer was a unilateral decision by Pfizer based on the Pharmaceutical Act. Pfizer only set one 'free price', which was replaced by law by the regulated price set by Spanish authorities pursuant to Article 90 of the Pharmaceutical Act (and Article 100(2) of the former Pharmaceutical Act[22]) for those products fulfilling the conditions established in this provision. In this respect, the CNC referred to the judgment of a first instance civil court of 27 April 2007[23] which confirmed that the application of the regulated price was conditional upon the fulfilment of the two requirements of public financing and dispensation of the product at issue in Spain.

The CNC also invoked Recommendation VI of the 'G10 High Level Group on innovation and provision of medicines in the European Union' of 7 May 2002, pursuant to which 'the Commission and Member States should secure the principle that a Member State's authority to regulate prices in the EU should extend only to those medicines

20 Case 39.184 *SP/Pfizer*.

21 Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices, OJ L 336/21 of 29.12.1999.

22 Act 25/1990, of 20 December.

23 Judgment of *Juzgado de Primera Instancia* of Valencia of 27 April 2007 in case 567/2003.

▶ GO TO TABLE OF CONTENTS

purchased by, or reimbursed by, the State. Full competition should be allowed for medicines not reimbursed by State systems or medicines sold into private markets.'[24]

2. The EAEPC/Laboratorios Farmacéuticos case

In the *EAEPC* case, the CNC rejected a complaint by the European Association of Euro-Pharmaceutical Companies (EAEPC) against several pharmaceutical companies in relation to their 'double pricing' systems which, according to the EAEPC, infringed Articles 1 LDC and 81 EC (now Article 101 TFEU).

The EAEPC had already lodged a complaint against Pfizer for the same facts before the European Commission, which dismissed it for lack of Community interest.[25]

As in the above mentioned *Spain Pharma* case, the CNC distinguished between 'double pricing' and 'free pricing' systems. According to the CNC, pharmaceutical companies set up just one price that is replaced by the regulated price fixed by the Administration when the conditions for the application of the latter (public financing and dispensation in Spain) are fulfilled. The CNC held that the regulated price is fixed in view of the public interest of the Spanish State -in that it relates to products financed with public funds- and cannot be extended to exported products. It also found that pharmaceutical companies need to know the place of dispensation of their products to be able to apply the regulated price and that, consequently, information systems whereby wholesalers should provide information as to dispensation in Spain did not affect competition.

Furthermore, the CNC discarded a possible concertation between pharmaceutical companies to apply their 'free pricing' systems. Again, the CNC stated that the establishment by these companies of information systems regarding dispensation in Spain could be explained by the need to comply with Article 90 of the Pharmaceutical Act.

Finally, the CNC rejected the EAEPC's allegations relating to the foreclosure of wholesalers. The CNC found no evidence of such foreclosure and held that pharmaceutical companies were free to determine the size of their distribution networks.

3. The judgments of the Audiencia Nacional

The *Spain Pharma* and *EAEPC* decisions of the CNC dismissing the complaints brought by parallel traders against the free pricing schemes adopted in 2006 by several manufacturers were appealed by the complainants before the *Audiencia Nacional* (AN), a national court competent to hear actions against the CNC's decisions and other important economic and criminal cases. In two (identical) judgments of 13 June 2011 and 05 December 2012, the court annulled the CNC's decisions.

The AN held that the compatibility of the free pricing schemes with the new pharmaceutical legislation, to which the CNC had devoted a great part of its reasoning, was 'not enough to conclude that there has been no infringement of Articles 81 EC and 1

24 http://ec.europa.eu/health/ph_overview/Documents/key08_en.pdf.

25 Decision of 8 August 2006.

GO TO TABLE OF CONTENTS

LDC'. Similarly, the court rejected that several rulings from the Spanish Supreme Court confirming the compatibility of the said legislation with EU law (in particular the free movement of goods) were also not sufficient to discard a possible incompatibility of the pricing schemes with the competition rules.

As regards the CNC's second line of reasoning, that Pfizer had only established one price and no dual pricing, the AN applied the above-mentioned judgment of the then CFI (today General Court of the EU) in the *GSK Spain* case,[26] holding that the national legislation in question did not oblige pharmaceutical companies to apply different prices depending on whether their products were financed by public funds and dispensed in Spain. According to the AN, the relevant question is not whether or not the intervened prices were negotiated with the Administration but rather whether Spanish legislation left room for autonomous and independent behaviour by Pfizer. As the CFI concluded in its 2006 judgment (paras. 71-74 were quoted by the AN): 'Accordingly, it cannot be accepted that the national regulations in question required GW to apply, in the contracts which it concluded with Spanish wholesalers, prices which differ according to whether or not the medicines which it sells to them will be reimbursed by the Spanish sickness insurance scheme.'

In other words, Spanish legislation did not oblige manufacturers to apply a different (higher) price to exported medicines. Hence, GSK had room for autonomous behaviour when setting the export price, to which Article 101 TFEU could apply. The judgments of the AN reject that this situation would have changed under Article 90 of the new Pharmaceutical Act of 2006.[27] The AN therefore denied that the free pricing schemes were different from GSK's original dual pricing scheme since Spanish legislation did not fix a price for medicines that are *not* financed by the State, and declared that they therefore posed the same competition problems as the latter, quoting the European Commission's decision to reject a complaint from the EAEPC in its support.[28]

Nonetheless, the AN acknowledged that the issue of whether prices were negotiated with the Administration or simply imposed by the latter could be relevant for the analysis of the fulfilment of the four conditions of Article 101(3) TFEU, but not as regards the question of whether the pricing schemes restricted competition. In this respect, the AN applied the ECJ's judgment in *GSK Spain*, holding that the agreements in question limited parallel trade and therefore restricted competition by 'object', irrespective of the particular legal and economic context of the pharmaceutical sector.

The AN also followed the ECJ in holding that an agreement that restricts parallel trade may benefit from an exemption pursuant to Art. 101(3) TFEU if it fulfils the four conditions established therein. The judgments admit that the peculiarities of the pharmaceutical sector, in particular as regards the regulation of prices, must be taken into account when assessing whether such pricing schemes fulfil the conditions of

26 Judgment in GlaxoSmithKline Services Unlimited v. Commission, paragraph 9 above, EU:T:2006:265.

27 Act 29/2006, of 26 July, on Guarantees and Rational Use of Medicinal Products and Medical Devices, Official State Gazette number 178 of 27.07.2006.

28 Communication of 08.08.2006, SG-Greffe (2006) D/204521.

▶ GO TO TABLE OF CONTENTS

Article 101(3) TFEU. The AN did not analyze the fulfilment of those conditions, but acknowledged that the legal and economic context may be important to that analysis. A relevant factor in that respect might be the disputed question of whether prices are unilaterally fixed by the Health Authorities or 'negotiated' with pharmaceutical companies, which the judgments of the AN analyze at length, although no conclusion is reached on the impact of the price-setting procedure on the application of Article 101(3) TFEU.

4. The judgment of the Supreme Court

The judgments of the AN were appealed before the Supreme Court, which delivered its first judgment in the Pfizer appeal on 03 December 2014, fully upholding the AN's first ruling of 13 June 2011.

The Supreme Court (TS) rejects that there was no 'agreement' for the purposes of Article 101 TFEU between Pfizer and its wholesalers, since Pfizer had concluded supply contracts with each wholesaler which included the 'free pricing' provisions. The contracts expressly make reference to the application of a 'Pfizer price' (free price) to exports and the 'intervened price' to pharmaceuticals financed by the Spanish State and dispensed in the national territory. According to the TS, these clauses may have as their main object to impede or restrict parallel exports of pharmaceuticals into other Member States of the EU. Given that the CNC had not analyzed the restrictive object of the clauses in question, the language employed by the TS does not conclude that there actually is a restriction by object but rather asks the competition authority to examine and verify these clauses in light of the *GSK Spain* case law of the European Courts.

The TS recalls that the judgment of the AN rests on the ECJ's ruling in *GSK Spain*, where the Court held that the application of different prices to financed medicines dispensed in Spain and to exported medicines amounted to a restriction of competition contrary to Article 101(1) TFEU. The TS holds that the contracts between Pfizer and its wholesalers include a system of 'selective double pricing' which may prima facie limit parallel trade and thus restrict competition by object, thus rejecting the theory of a 'unilateral free pricing system' put forward by Pfizer on the basis of Article 90 of the current Pharmaceutical Act.

The TS concludes that the ECJ's case law is mandatory for the CNC's analysis of the effects of Pfizer's agreements with wholesalers on the structure of the internal market and of whether they hinder the integration of national markets, before evaluating whether the four conditions of Article 101(3) TFEU are met.

It is foreseeable that the Spanish Supreme Court will rule on the still pending appeal against the second judgment of the *Audiencia Nacional* relating to the EAEPC's complaint to the CNC and the free pricing systems introduced by six pharmaceutical companies in identical terms to those of the December 2014 ruling.

▶ GO TO TABLE OF CONTENTS

V. Outlook: the future evaluation of Article 101(3) TFEU

As a consequence of the Supreme Court's ruling of December 2014, the Spanish competition authority (now the *Comisión Nacional de los Mercados y la Competencia*, CNMC) on 5 March 2015 formally re-opened the proceedings against Pfizer's free-pricing system.

After the rulings delivered by the Court of First Instance and, on appeal, the European Court of Justice in the *GSK Spain* case and the ensuing judgments by the Spanish *Audiencia Nacional* and Supreme Court, it has become clear that the solution to the distortions of competition caused by parallel trade in pharmaceuticals is to be found in the third paragraph of Article 101 TFEU.

Although the courts acknowledged that there is a distortion of genuine competition due to the fact that the prices of these products are fixed by various Member States, a circumstance that makes parallel exports from low-priced to higher priced countries possible in the first place, the ECJ has nonetheless concluded that any limitation of parallel trade, also in such intervened products, restricts competition 'by object' within the meaning of Article 101(1) TFEU.

It is also clear from the CFI's judgment that 'the conduct consisting in establishing, by contract, a system of differentiated prices prohibiting the Spanish wholesalers dealing with GW from purchasing at that price (the Clause 4A price) medicines which they will resell in other Member States, and obliging them to purchase those products at a higher price (the Clause 4B price), is not imposed by the Spanish regulations' (para. 73). Article 101 TFEU therefore fully applies to such a system of differentiated prices even if the prices of reimbursable medicines are fixed wholly independently by the Spanish authorities and are binding.

This is why the solution of the problem created by parallel trade in a product with intervened prices can only be found in the third paragraph of Article 101 TFEU.

Although the *GSK Spain* case has not definitively settled whether a system of differentiated prices fulfills the four requirements of Article 101(3) TFEU, there are indications in the judgments of both EU Courts that at least some of these four conditions may be fulfilled, bearing in mind the specific circumstances of the pharmaceutical sector.

Both the judgments of the EU Courts and those of the Spanish courts confirm that an agreement that restricts parallel trade –and thus, according to the ECJ, competition 'by object' within the meaning of Article 101(1) TFEU— may nonetheless benefit from an exemption pursuant to the third paragraph of Article 101 if it fulfils the four cumulative conditions established in that provision, i.e.,if it creates efficiencies, benefits consumers, the restriction is indispensable and it does not eliminate compe-

▶ GO TO TABLE OF CONTENTS

tition on the market. Both judgments include important statements as to the possible fulfilment of at least some of these conditions.

On the first condition of Article 101(3) —the generation of efficiencies— the EU Courts have acknowledged that an agreement restricting parallel trade may generate efficiencies by allowing pharmaceutical companies to increase their investment in R&D. According to the ECJ, it is enough that such an efficiency is 'sufficiently likely'. Also, there is no need for all additional funds recovered by limiting parallel trade to be invested in R&D. The Court of Justice also confirmed that to determine whether an agreement generates efficiencies, it may be necessary to take into account the nature and specific features of the sector concerned. According to the judgment of the *Audiencia Nacional* it might also become relevant whether intervened prices are actually the result of a negotiation between manufacturers and the Administration or unilaterally imposed by the latter.

As regards the second requirement of benefiting consumers, an increase in R&D should normally benefit consumers (i.e., patients) because in a competitive industry it is in the interest of pharmaceutical companies to reinvest funds in R&D due to intense competition in innovation.

Regarding the fourth requirement of 'no elimination of competition', the CFI held that an agreement restricting parallel trade limits intrabrand (price) competition between exporting wholesalers and distributors in the country of importation, but does not exclude it completely since there is price competition following generic entry. Furthermore, the restriction of competition allows an increase in competition based on innovation (interbrand competition), which is usually regarded to weigh more than intrabrand competition. As the CFI put it in its judgment, 'in those circumstances, it was still necessary, in accordance with the case-law cited at paragraph 109 above, to assess what form of competition must be given priority with a view to ensuring the maintenance of effective competition sought by Article 3(1)(g) EC and Article 81 EC. '

While there seem to be reasonable arguments to argue that these three conditions of Article 101(3) TFEU are met, neither the judgments of the CFI and the ECJ nor those of the Spanish AN and TS say a word on the crucial requirement of 'indispensability' in that provision. This third condition of Article 101 (3) requires balancing the restriction against the resulting efficiencies and thus applying the proportionality principle to assess whether the restriction is actually necessary to achieve these efficiencies or goes beyond what is necessary. Issues such as the level of prices that ensures an optimal financing of R&D, or the need to exclude or only limit parallel trade, might come up in the forthcoming discussions of this requirement.

▶ GO TO TABLE OF CONTENTS

VI. Conclusion

The rulings of both the EU Courts and the Spanish *Audiencia Nacional* and Supreme Court show that the decade-long discussion in the *GSK Spain* case about the merits of parallel trade in products with intervened prices eventually has convinced competition authorities in Europe that parallel trade in such circumstances does not merit protection. This can be seen in the decisions of the Spanish competition authority delivered in the aftermath of the GSK case. In the *EAEPC* case, the CNC held that 'it would make no sense to extend the fixing of prices by the Spanish State according to public interest criteria to other territories or that products for exportation were affected by the intervened prices determined in Spain, limiting in an unjustified manner the [fundamental] freedom of producers [to set their prices]'. In Spain, severe supply shortages due to parallel exports with the involvement of pharmacies have recently even led to criminal prosecution of such practices.

As the CFI confirmed in its *GSK* ruling, the effects of parallel trade on intrabrand competition are 'marginal', because price differences are usually entirely pocketed by parallel traders and not passed on to consumers in the Member State of destination. As the CFI reminds us in its ruling, the Commission itself has publicly conceded in a number of official communications, notably Communication COM(1998) 588 final, the ambiguous impact of parallel trade of medicines on the welfare of final consumers, recognizing that unless parallel trade can operate dynamically on prices, it creates inefficiencies because most of the financial benefit accrues to the parallel trader rather than to the health care system or the patient.[29]

It must therefore be questioned whether the Treaty's competition rules may be employed to harmonize the prices of pharmaceuticals throughout the internal market.[30] While such price harmonization is legitimate where prices are freely set by manufacturers, where there are price differentials due to regulation or State intervention, as is clearly the case in the pharmaceutical sector, it is not legitimate to impose price harmonization through a strained application of the competition rules that promotes parallel trade. As the CFI expressed it in its *GSK* judgment, in the pharmaceutical sector parallel traders 'are the vectors of artificial competition and not of effective competition within the meaning of Article 3(1)(g) EC and Article 81 EC' (para. 146).

---

29 Communication COM(1998) 588 final of 25 November1999 on the single market in pharmaceuticals, p. 6.

30 On this question, see Martínez Lage, S. and Martínez-Lage, P.: '*Pursuing market integration through the application of EC competition rules. A critical perspective*', in *Mélanges en hommage à Georges Vandersanden. Promenades au sein du Droit Européen*. Bruylant : Bruxelles 2008, pp. 593-612.

▶ GO TO TABLE OF CONTENTS

The goal of price harmonisation in the pharmaceutical sector may thus only be achieved via harmonisation within the boundaries established in the Treaty on the EU's legislative competences in that field and not through the backdoor of allowing parallel trade in a sector in which a common market does not (yet) exist. As the CFI put it in the *Bayer Adalat* judgment,[31] the Commission is not entitled, under the system of the Treaty, to attempt to achieve the harmonization of prices in the pharmaceutical products market, 'by enlarging or straining' the scope of the rules applying to undertakings, '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'. The CFI did indeed recall in *Bayer Adalat* that it is settled case law that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities. The CFI also stated that[32] in any event, the Commission's conviction that parallel imports will in the long term bring about the harmonization of prices of pharmaceutical products was completely unfounded, and it also clarified that the Commission could not rely, in support of its decision, on its claim that it is not acceptable for parallel imports to be hindered so that pharmaceutical companies may impose excessive rates in countries not applying any price control to compensate for lower profits in Member States where there is a stricter control of prices.

Since the CNC's 2009 decisions to dismiss the complaints of parallel traders against so-called free pricing schemes have been overturned by the Spanish courts, it is now for the CNC's successor, the CNMC, to articulate this policy within the framework of the third paragraph of Article 101 TFEU.

31 Judgment in *Bayer AG v. Commission*, para. 12 above, EU:T:2000:242.

32 Para. 181 of the judgment.

▶ GO TO TABLE OF CONTENTS

Editors
Sir David Edward
Jacquelyn MacLennan
Assimakis Komninos

Ian S. Forrester QC LL.D.

A Scot without Borders
Liber Amicorum - Volume II

It is with great pleasure that we present this Liber Amicorum to Ian Stewart Forrester QC LL.D. on the year of his 70th birthday and at this point of transition in his extraordinary professional life. This two-volume Liber Amicorum is a collection of tributes to Ian Forrester's outstanding career and of a series of articles signed by prominent academics and practitioners around the world on the most current topics in EU law and policies, competition law, human rights and intellectual property.

Born in Glasgow from a Scottish family, Ian Forrester practiced law in multiple cities, Brussels, New York and London, to mention some. He arrived in Brussels in 1973 as one of the first generation of UK lawyers at the time when the UK joined the European Union. He participated in many of the leading cases in the formation of key principles of EU law, particularly EU competition law such as Bosman, Bullock (Distillers), GlaxoSmithKline, Servier, Pfizer, Magill, IMS Health and Microsoft. Ian Forrester lived these and other cases professionally and academically, debating them with students, professors and researchers. He has been a mentor to many younger lawyers and is also a prolific writer of seminal articles. His good spirits and quirky sense of humour have made him friends and professional connections all over the world and this Liber Amicorum is an occasion to mark the outstanding merits of a remarkable man and express the long lasting and affectionate friendship.

▶ GO TO TABLE OF CONTENTS

ISBN 978-1-939007-28-5
90000
9 781939 007285

Concurrences
Review, Bulletin, Books, Conferences

190 € VAT included