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PARALLEL TRADE IN PHARMACEUTICAL PRODUCTS WITHIN THE INTERNAL MARKET: THE RECENT *GLAXO* JUDGMENT OF THE E.C.J.

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I. INTRODUCTION

During the 50 years of history of European Community (E.C.) competition law, agreements restricting parallel trade within Member States of the Community have been consistently held to be restrictive of competition by their nature and very unlikely to be exempted under Article 81(3) of the E.C. Treaty. The strict stance towards such agreements is better explained by the role competition policy has always played in the elimination of barriers to trade in E.C. law than it is by efficiency considerations.¹

The particular features of the pharmaceutical sector challenge the monolithic stance of Community institutions towards parallel trade restrictions. Unlike other sectors, the price of pharmaceuticals is decisively influenced by regulation.² What is more, regulation diverges considerably from one Member State to another, depending on the policy choices made at the national level.³ The resulting price differences constitute a natural incentive for parallel traders who purchase pharmaceutical products in low-price Member States and resell them in the Member States where prices for medicines are higher.⁴

If the role and the implications of regulation in the pharmaceutical sector are considered, it appears that a *per se* approach towards parallel trade restrictions amounts to exporting policy choices from low-price countries to other Member States or, as has been put, to defeating “the wishes of the government.”⁵

In this regulatory and economic context it is not surprising that pharmaceutical companies have taken active steps to restrict parallel trade, in spite of the clear prohibition spelled out in Article 81(1) E.C. For instance, pharmaceutical companies have attempted to circumvent the application of that provision—which can only be triggered by the presence of an “agreement”—by

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¹ See David J. Gerber, *The Transformation of European Community Competition Law?*, 35 HARV. INT’L L.J. 97 (1994).

² Opinion of Advocate General Jacobs, Case C-53/03, *Syfait v. GlaxoSmithKline*, 2005 E.C.R. I-4609, ¶ 77-78.

³ *Id.*

⁴ *Id.*

⁵ Valérie Junod, *An End to Parallel Imports of Medicines? Comments on the Judgment of the Court of First Instance in GlaxoWellcome*, 30 WORLD COMPETITION L. & ECON. REV. 291, 304. A similar debate took place during the 1970s and the early 1980s, when there were important divergences in the degree of protection of pharmaceuticals under national patent laws. In these cases, it was argued that favoring the free movement of goods over the national law amounted to exporting policy choices from countries granting weaker protection to pharmaceuticals. See Case 15/74, *Centrafarm v. Sterling Drug*, 1974 E.C.R. 1147; Case 187/80, *Merck v. Stephar*, 1981 E.C.R. 2063.

unilaterally restricting the supplies to wholesalers in low-price countries.⁶ The issue at the center of the recent *Glaxo* judgment⁷ of the European Court of Justice (E.C.J.) involves a different regulatory strategy. In *Glaxo*, Glaxo Wellcome⁸ (Glaxo) purported to implement a dual-price mechanism, whereby prices proposed to wholesalers in Spain changed depending on whether the product was intended to be sold in Spain or elsewhere through parallel trade.⁹

II. THE AGREEMENT AND THE 2001 DECISION OF THE COMMISSION

More than eleven years ago, in March 1998, Glaxo notified the European Commission (the Commission) of its new general sales conditions (the Sales Conditions). The notified model contract provided for a dual-price system for the sale of eighty-two products (including eight products that Glaxo considered to be the main candidates for parallel trade between Spain and the United Kingdom).¹⁰ More precisely, Article 4 of the Sales Conditions established different prices for (i) products financed by funds of the Spanish Social Security or by Spanish public funds and marketed at the national level and (ii) all other products.¹¹ Glaxo did not contest that the main intention of the agreement was to limit parallel trade between Spain and other Member States.¹² In a decision of May 8, 2001 (the Commission Decision), the Commission found that Glaxo had infringed Article 81(1) E.C. and that it could not benefit from an exemption under Article 81(3) E.C.¹³ Glaxo brought an action before the Court of First Instance (C.F.I.) requesting the annulment of the Commission decision in its entirety.

III. THE JUDGMENT OF THE C.F.I.

The C.F.I. agreed with the Commission that Glaxo's Sales Conditions infringed Article 81(1) E.C. but rejected the Commission's finding that the agreement¹⁴ had as its *object* a restriction of competition.¹⁵ Most significantly, the C.F.I. held that parallel trade must be protected only "in so far as it gives final consumers the advantages of effective competition in terms of supply or price,"¹⁶ thus interpreting the market integration objective in the light of consumer welfare. Taking into account the particularities of pharmaceutical markets the C.F.I. concluded that:

As the prices of the medicines concerned are to a large extent shielded from the free play of supply and demand owing to the applicable regulations and are set or

⁶ See Joined Cases C-2/01 P and C-3/01 P, *Bundesverband der Arzneimittel-Importeure v. Bayer*, 2004 E.C.R. I-23.

⁷ Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, *GlaxoSmithKline v. Comm'n and Comm'n v. GlaxoSmithKline and EAEP v. Comm'n and Aseprofar v. Comm'n*, 2009 WL 3171536 (Oct. 6, 2009).

⁸ More precisely, the notification was filed by Glaxo Wellcome SA, a Spanish subsidiary of Glaxo Wellcome plc (now GlaxoSmithKline Services Unlimited).

⁹ Commission Decision 2001/79/EC, Relating to a Proceeding Pursuant to Article 81 of the EC Treaty, 2001 O.J. (L 302) 1, recital 116.

¹⁰ *Id.* recitals 13, 15.

¹¹ *Id.* recital 19 (reproducing clause 4 of the Sales Conditions).

¹² *Id.* recital 116.

¹³ *Id.* art. 1–2.

¹⁴ For the analysis of the existence of an agreement between Glaxo and the Spanish wholesalers, see Case T-168/01, *GlaxoSmithKline v. Comm'n*, 2006 E.C.R. II-2969, ¶¶60–90.

¹⁵ *Id.* ¶ 147.

¹⁶ *Id.* ¶ 121.

controlled by the public authorities, it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers.¹⁷

The Court then turned to the analysis of the anti-competitive *effect* of the agreement and concluded that such an effect existed, as consumer welfare (in the form of lower prices) is diminished by the absence of the Spanish wholesalers in the intra-brand competition in the Member States of destination of the parallel trade.¹⁸

Concerning the efficiency claims under Article 81(3) E.C., the C.F.I. criticized the Commission for not sufficiently taking into account the arguments and evidence submitted by Glaxo to prove the existence of a contribution to the promotion of technical progress (i.e. innovation).¹⁹ Consequently, the C.F.I. annulled the Commission Decision in so far as it rejected Glaxo's request for an exemption.²⁰ Both Glaxo and the Commission appealed to the E.C.J. against the judgment.

IV. THE JUDGMENT OF THE E.C.J.

In a judgment of October 6, 2009, the E.C.J. rejected the lower court's approach towards Article 81(1) E.C. and provided certain clarifications on the application of Article 81(3) E.C.

A. *A confirmation of the traditional stance towards parallel trade under Article 81(1)*

The E.C.J. reiterated its traditional stance towards agreements restricting parallel trade under Article 81(1) E.C. Accordingly, the dual-pricing system was deemed to have an anti-competitive *object*.²¹ The specific features of the sector in which the agreement is concluded do not alter that conclusion.²² This principle is based on the fact that parallel trade restrictions "frustrate the Treaty's objective of achieving the integration of national markets."²³

The E.C.J. categorically discarded the C.F.I.'s view that the above principle only applies in so far as the agreement deprives the consumer of the advantages of effective competition; the Court held that neither the text of Article 81(1) E.C. nor the case law support the position of the C.F.I.²⁴ More precisely, the Court noted:

[T]here is nothing in that provision to indicate that only those agreements which deprive consumers of certain advantages may have an anti-competitive object. Secondly, it must be borne in mind that the Court has held that, like other

¹⁷ *Id.* ¶ 147.

¹⁸ *Id.* ¶ 190.

¹⁹ *Id.* ¶¶ 303, 308.

²⁰ *Id.* ¶ 317.

²¹ *GlaxoSmithKline v. Comm'n and Comm'n v. GlaxoSmithKline and EAEPC v. Comm'n and Aseprofar v. Comm'n*, 2009 WL 3171536, ¶¶ 59–60.

²² *Id.*

²³ *Id.* ¶ 61.

²⁴ *Id.* ¶ 62.

competition rules laid down in the Treaty, Article 81 EC aims to protect not only the interests of competitors or of consumers, but also the structure of the market and, in so doing, competition as such. Consequently, for a finding that an agreement has an anti-competitive object, it is not necessary that final consumers be deprived of the advantages of effective competition in terms of supply or price.²⁵

Accordingly, “by requiring proof that the agreement entails disadvantages for final consumers as a prerequisite for finding an anti-competitive object . . . the [C.F.I.] committed an error of law.”²⁶ The E.C.J.’s strict approach towards Article 81(1) E.C. is, however, counterbalanced by taking into account the sector-specific features in the (prospective) analysis of the efficiency gains under paragraph (3) of the same Article.

B. The features of the pharmaceutical sector are considered under Article 81(3)

The E.C.J. judgment clarified that Article 81(3) E.C. is the appropriate forum to take the particular features of the pharmaceutical into consideration. In this regard, the E.C.J. acknowledged that there were no reasons *a priori* why the agreement notified by Glaxo could not qualify for an exemption under Article 81(3) E.C.

First, the E.C.J. noted that the C.F.I. had not erred in law by criticizing the Commission for not taking Glaxo’s arguments seriously into consideration.²⁷ According to the E.C.J., nothing in the C.F.I.’s interpretation of Article 81(3) E.C. altered well-established principles in E.C. law whereby (i) the burden of proof to establish that the conditions of Article 81(3) E.C. are fulfilled lies with the undertaking claiming the benefit of an exemption, and (ii) judges exercise limited review regarding “complex economic assessments.”²⁸

Secondly, regarding the requisite standard of proof, following the *Glaxo* judgment, undertakings invoking the benefit of an exemption must provide evidence that the occurrence of the efficiency gains entailed by the agreement is “sufficiently likely.”²⁹

Thirdly, and most significantly, the E.C.J. found that the C.F.I. had rightly criticized the Commission decision for not taking into consideration the “specific structural features” of the pharmaceutical sector.³⁰ Indeed, an assessment of the exemption under Article 81(3) E.C. “may require the nature and the specific features of the sector concerned by the agreement to be taken into account if its nature and those specific features are decisive for the outcome of the analysis.”³¹

²⁵ *Id.* ¶ 63.

²⁶ *Id.* ¶ 64.

²⁷ *Id.* ¶¶ 78–88.

²⁸ *Id.*

²⁹ *Id.* ¶ 93.

³⁰ *Id.* ¶ 104.

³¹ *Id.* ¶ 103.

V. CONCLUSION

There are reasons to welcome the E.C.J. judgment in *Glaxo*. In line with a similar ruling in *Sot Lelos*,³² the E.C.J. has acknowledged that the specific features of the pharmaceutical sector are sufficiently important to refine its traditionally inflexible approach towards restrictions of parallel trade. There is moreover every reason to praise the legal technique through which these specific features are accommodated into the assessment. Unlike the C.F.I., the E.C.J. chose not to interpret the notion of restriction of competition under Article 81(1) E.C. as an amalgam of consumer welfare and market integration considerations. Instead, the *Glaxo* judgment of the E.C.J. clarifies that market integration is an objective worthy of being pursued in and of itself. Finally, by shifting the assessment of the potential welfare-enhancing features of Glaxo's pricing policy to Article 81(3) E.C., the E.C.J. reiterated one of the most important principles of E.C. competition law, which is that there is no such thing as a *per se* restriction of competition for which the benefit of Article 81(3) E.C. is excluded.

³² Joined Cases C-468/06 and C-478/06, *Sot. Lélos v. GlaxoSmithKline*, 2008 E.C.R. I-7139.