EU General Court Dismisses Parallel Trade Group's Dual-Pricing Complaint Against GSK

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On September 26, 2018, the EU General Court[1] (the Court) upheld the European Commission's refusal to reinvestigate GlaxoSmithKline SA's (GSK) Spanish "dual-pricing" distribution arrangements, 20 years after the alleged conduct to which the complaint related.

This long-running case had culminated in the EU Court of Justice's 2009 verdict faulting the Commission's original case for not properly evaluating potential efficiencies from limiting parallel trade. On remittal, the Commission concluded in 2014 that the case was no longer a priority and declined to reinvestigate.

Notably, in its September 2018 decision, the Court confirmed that the Commission was right to drop the case, notwithstanding allegations by parallel traders that "dual-pricing" schemes — which purportedly discourage cross-border trade — proliferated in the aftermath of GSK's practices. Such allegations normally would have been expected to attract Commission interest.

The Court found the Commission lawfully deprioritized the case, because GSK's conduct had long since ceased; national authorities or courts might address allegations of unlawful conduct at a local level; and there was no evidence other dual-pricing schemes were linked to GSK's conduct — rather, 2006 changes to Spanish pharmaceutical pricing legislation likely contributed to the proliferation.

In parallel, the Spanish authorities have rejected similar complaints at a national level and approved pharmaceutical companies' pricing arrangements. The parallel traders association is considering an appeal in the case before the European Court of Justice and also has been an active complainant before the Spanish authorities.

Pharmaceutical companies can take comfort that these types of pricing programs have been approved by national authorities, and the Commission has deprioritized further inquiry. But while complainants remain active, pricing programs will continue to require careful legal review.

Background of the Case

In March 1998, GSK notified the Commission of its new general sales conditions to authorized wholesalers in Spain. The agreement included a "dual-pricing" mechanism, which involved GSK charging parallel traders more than those who sold on the domestic market in Spain. In 1999, the European Association of Euro-Pharmaceutical Companies (EAEPC) lodged a complaint with the Commission concerning GSK's dual-pricing policy, requesting that the Commission refuse to grant GSK the negative clearance or exemption it sought.

In 2001, the Commission found that GSK's system infringed competition law. The decision was partially annulled by the General Court in 2006 on the ground that the Commission had not carried out an adequate examination of whether the conditions for exemption laid down in Article 101(3) of the Treaty on the Functioning of the European Union (TFEU) had been fulfilled.[2] The Court of Justice upheld the relevant General Court judgments.[3] Based on the Court of Justice's rulings, GSK formally withdrew its application for an exemption.

[1] Case T-574/14, *EAEPC v Commission.*

[2] Case T-168/01, *GlaxoSmithKline Services v Commission.*

[3] Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, *GlaxoSmithKline Services and Others v Commission and Others.*

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In May 2014, the Commission rejected the EAEPC's 1999 complaint,[4] which had undergone multiple revisions. The Commission rejected the complaint based on lack of European Union interest in continuing the investigation due to (i) the cessation of the conduct at issue in October 1998, (ii) the absence of persisting effects, and (iii) the fact that the national courts and authorities were well-placed to handle the issues raised.

Ruling of the General Court

The General Court upheld the Commission's decision rejecting the EAEPC's 1999 complaint, finding that the Commission correctly examined whether the European Union had an interest in continuing the investigation and correctly concluded it did not. In particular, the General Court determined that the pervasiveness of dual-pricing practices in Spain could not be attributed to the system that GSK briefly implemented in 1998. The Court concluded that the Commission did not make any error of assessment in finding that "*the purchase prices and volumes that Spanish wholesalers currently face in order to export those 82 medicines are determined by today's market dynamics rather than by GSK's conduct*," which had ceased in 1998.[5] In this regard, the Commission had concluded in its 2014 decision that the widespread use of dual-pricing systems was linked to, among other factors, national regulation that entered in force in 2006 in Spain.

Conclusion

As the GSK Spain dual-pricing saga may continue, the application of the conditions for exemption set out in Article 101(3) TFEU for dual-pricing systems remains unclear. The EU has not pursued any other dual-pricing case since 2001, apart from the investigation it opened into alleged dual-pricing practices in Spain shortly before rejecting the EAEPC complaint.[6] At the member state level, similar complaints were rejected in relation to pharmaceutical distribution agreements in Spain. In 2017, the Spanish competition authority (CNMC) approved a pharmaceutical company's distribution arrangements on the basis that it only set one price for its goods, with another price fixed by Spanish regulation. The CNMC also recently concluded an investigation into the potential establishment of a dual-pricing distribution system among pharmaceutical companies, including notably Merck Sharp & Dohme de España SA, Novartis Farmacéutica SA, Lilly SA, Sanofi-Aventis SA and Johnson & Johnson unit Janssen-Cilag SA. The CNMC decision, published in September 2018, concluded that there was no collusion on the dual-pricing, as coordination on the timing of contract modifications could be explained by the entry into force of the 2006 regulation.[7] Although there will likely be further appeals, the cases confirm that the Spanish authorities take the view that pharmaceutical companies may lawfully implement these pricing arrangements. Careful legal review, however, is essential to assess the legality of the arrangements in the context of national pharmaceutical pricing and regulatory laws.

[4] Case COMP/AT.36957 — *Glaxo Wellcome*.

[5] Case T-574/14, *EAEPC v Commission*, para. 117.

[6] AT.39973 — Pricing schemes for distribution of medicines in Spain.

[7] S/DC/0608/17: *EAEPC vs Laboratorios Farmacéuticos*.

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