

Restrictions of parallel trade in pharmaceuticals

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PARALLEL TRADE - what is it?

- A product is sold through established distribution channels in country A and in country B
- There are substantial price differences for the product between country A and country B
- To such extent that it becomes profitable for third parties to buy the product in country A and sell it in country B
- Thus creating an unofficial channel of distribution (“sometimes also referred to as “gray imports”)

PARALLEL TRADE - different in pharma?

- There are **regulatory circumstances** specific to the pharmaceutical sector:
 - **State regulation** is the direct cause of the significant **price differences** that makes parallel trade in pharmaceutical markets so profitable
 - the resulting distortions of the internal market have **not** been eliminated through **harmonisation** – health remains a Member State prerogative
 - commercial choices available to manufacturers, including withdrawal from a market that is no longer profitable, are substantially limited by **public service obligations and moral obligations**

PARALLEL TRADE – a tool for market integration in pharma?

- Given regulatory context, **questions** arise on whether:
 - attempts to limit parallel trade of pharmaceutical products are designed to maintain national price differences created by manufacturers **or rather** attempts to organise distribution in the most profitable manner?
 - the partitioning of the European markets for pharmaceutical products is the result of restraints of trade **or rather** a result of national regulation?
 - parallel trade of pharmaceutical products (necessarily) leads to price competition to the benefit of consumers **or rather** a windfall (mainly) for parallel traders?

PARALLEL TRADE - the law (also in pharma)

- Since market integration is one of the fundamental policy principles of the EU, limiting parallel trade has traditionally been treated as a hard-core restriction – that remains the case today, also in pharmaceuticals markets:
 - **export bans** are prohibited by EU competition law
 - can be caught by Article 101 TFEU as an **agreement or concerted practice** between independent parties
 - can be caught by Article 102 TFEU as an **abuse** if the undertaking concerned is **dominant** in the relevant market

PARALLEL TRADE – Art 101 TFEU case law

- “Agreed” supply quota systems – *Bayer*
- Bayer (France and Spain) reduced supplies to wholesalers to the level of domestic needs plus 10%.
- EC imposed fines.
- ECJ found that there was **no agreement** imposing an export ban, because Bayer did not:
 - in any way seek its wholesalers’ cooperation
 - systematically monitor the destination of the products
 - identify or penalize exporting wholesalers
 - set the quotas ex post or discriminate in their application

PARALLEL TRADE – Art 101 TFEU case law

- Dual prices - *GSK Spain*
- GSK decided to apply dual prices to Spanish wholesalers:
 - a price not exceeding the maximum set by the authorities for reimbursed, locally sold products; and
 - a freely established price for all other products, irrespective of destination.
- ECJ upheld EC finding that dual pricing is a **by object infringement**
- Nevertheless, such a scheme is **capable of exemption under Art 101(3) TFEU** insofar as the scheme can be shown to bring about appreciable objective advantages that outweigh the anticompetitive effects
 - EC had been wrong to dismiss GSK's argument on the contribution to innovation and the improvement in the distribution of pharmaceutical products that flowed from its distribution and pricing policy, which were "**relevant, reliable and credible**"

PARALLEL TRADE – Art 102 TFEU case law

- Unilateral supply quotas - *GSK Greece (I and II)*
- In response to supply shortage caused by significant parallel trade from Greece, GSK decided to:
 - cease all supplies to wholesalers and instead sell to a single logistics provider, and
 - on reinstating sales, not to meet orders in full but limit to volumes required for in-market demand + margin
- Question put to the ECJ - is refusal by a dominant pharmaceutical manufacturer to meet in full orders placed by wholesalers an abuse, in particular if orders include significant volumes essentially destined for parallel trade?
- In *GSK Greece I*, AG Jacobs suggested that the particular features of the pharmaceutical markets could serve as **objective justification**, pointing to minimal benefit of parallel trade to final consumers, national price controls removing normal competitive conditions, and a need to limit parallel trade to safeguard investments in R&D.

PARALLEL TRADE – Art 102 TFEU case law

- In *GSK Greece II* the ECJ did not follow that approach, but instead applied a more traditional analysis on refusal to deal.
- It held that Art 102 applies to behavior that excludes *all* parallel trade, but that it is legitimate for a dominant supplier - in order to restrict parallel trade – to refuse to meet orders of existing customers if:
 - the parallel trade **threatens the legitimate commercial** interests of the manufacturer;
 - the **orders are out of the ordinary**, having regard to the previous business relations between that wholesaler and the manufacturer and having regard to the in-market requirements of the particular Member State; and
 - the refusal to supply is **reasonable and proportionate to the threat posed** to the manufacturer's commercial interests.

PARALLEL TRADE – Outlook

- Case law is well settled, on Art 101 and Art 102 TFEU.
- EC remains likely to intervene in case of a clear infringement, but otherwise has not shown any interest in pursuing these cases since the *GSK Greece* and *GSK Spain* rulings
 - dismissed complaint brought by EAEPC – the European Association of Euro-Pharmaceutical Companies – in *GSK Spain* based on “lack of Community interest”, and the EAEPC appeal against the EC’s decision not to pursue an investigation also was dismissed by the General Court in 2018
- National competition authorities also do not seem to be pursuing cases
 - national health regulatory authorities may rather support supply quotas that help stem shortages,
 - in an effort to limit shortages, numerous Member States have legislated to stem exports of pharmaceuticals.
- Other possible battlegrounds?
 - parallel trade in the context of excessive pricing? (*Aspen Italy*)
 - interplay with potential regulation to address access to medicines - price transparency, supply obligations, ...?