PARALLEL TRADE IN THE PHARMACEUTICAL SECTOR WITHIN THE EUROPEAN UNION

Author: João Pedro Sousa Leal de Castro Mendes

Supervisor: Prof. Dr. João Confraria

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LLM in International Business Law
Catholic University of Portugal

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Summary (Conclusion)

The pharmaceutical market is a complex market. It is characterised by high levels of price and supply regulation, high sunk costs, and the key role played by patents and innovation in driving competition. Price disparity within the market leads to the possibility of arbitrage, whereby parallel traders will take that opportunity by exporting legally acquired pharmaceutical products from low price Member States to high price Member States, without the consent of the manufacturer. This opportunity exists because internal market rules, as interpreted by the European Court of Justice, dictate that Member States cannot restrict trade based on the existence of different regulatory regimes.

Pharmaceutical companies argue that there are, in essence, several geographical pharmaceutical markets within the European Union. Each Member State has its own market, with its own regulatory characteristics. Pharmaceutical company's ability to profitably sell their products at low price countries is undercut if parallel traders are allowed to exploit arbitrage opportunities without manufacturers being able to act to deter such activities. This may lead them to be forced to leave such markets altogether, or to invest less in R&D.

The European Commission, and others, including Member States that believe they benefit from parallel trade, argue that there is a single market in pharmaceuticals, and that public restraints on trade cannot be replaced by private restraints on trade. Pharmaceutical companies enjoy considerable bargaining power during price negotiations with public authorities, too, and there is no causal link between decreased revenues resulting from parallel trade and a loss of incentive to conduct research in such an innovative market.

The European Courts determined, in *Adalat*, that an agreement concerning an

export ban is anticompetitive, but could not find such an agreement within the context of that case. It was not enough that combining obligations to supply on the part of the wholesalers with supply quotas imposed by *Bayer* had an effect similar to that of an export ban, as the Courts could not find any meeting of the minds between *Bayer* and its wholesalers.

In *Syfait*, AG Jacobs opined that the pharmaceutical companies had a good point, and that the internal market in pharmaceuticals was being partitioned by lack of regulatory harmonisation, not through the conduct of pharmaceutical companies. He also considered that the consequences of unmitigated parallel trade would undercut a regulatory regime that aimed to maintain a constant supply of medicines available to the population of the EU. Pharmaceutical companies should not bear the burden of connecting a partitioned market, and doing so may lead to an even more fragmented market in the end.

In *Syfait II*, AG Ruiz-Jarabo Colomer disagreed with AG Jacobs. He pointed to the considerable bargaining power of pharmaceutical companies during price negotiations, as well as to their freedom to decide on their distribution systems. He also noted the favourable conditions that exist within the EU for an industry that focuses on R&D, as well as the fact that competition within the pharmaceutical sector is driven by innovation, which is an incentive in itself for pharmaceutical companies to invest in R&D.

The European Court of Justice attempted to strike a balance between, on the one hand, the single market imperative and, on the other hand, a dominant firm's capacity to protect its legitimate commercial interests. It ruled, citing its own relevant case-law, that a dominant undertaking was only forced to maintain ordinary supply to its longstanding customers, and that it was for national courts to determine whether that was the case. In addition, national courts also had to take into account how supply obligations applied to manufacturers and to

distributors in coming to their decision of whether or not conduct by a dominant firm constituted an abuse of a dominant position.

The ECJ also imposed on Member States the burden of addressing any supply shortages arising from parallel trade. As was noted above, an LSE study found that such action was taking place, as Member States with lower prices have been taking action to address the issue of parallel exports, though always taking care not to run afoul of internal market rules. There have also been efforts on the part of the European Commission to promote the creation of common guidelines on price regulations, as mentioned in note 15 above.

Though the ECJ ruled, in *GlaxoSmithKline*, that agreement that has as its purpose the restriction of parallel trade is anti-competitive by object, even in the pharmaceutical sector, it let the General Court's ruling stand where that Court had found that the Commission had not adequately assessed whether or not GSK's dual pricing scheme could be justified under (current) Article 101(3) TFEU. In other words, while dual pricing restricts competition by object, it may not be as difficult to justify that restriction as a means of regaining efficiency lost due to the regulatory structure that underpins the pharmaceutical market. The General Court, at least, seemed very open to the possibility, which will have made the Commission's task of justifying its decisions not to apply Article 101(3) TFEU much harder.

Ultimately, differing views on parallel trade of pharmaceuticals in the European Union are based on fundamentally different ways of looking at cost-bearing due to lack of regulatory harmonisation and also on the bargaining power of pharmaceutical companies and Member States when negotiating price levels. Different vantage points lead to strikingly different conclusions on the issue of supply quotas and parallel trade, in particular when it comes to whether or not a refusal to supply constitutes abusive conduct under Article 102 TFEU.

Ultimately, the European Court of Justice's decision on the matter is “the law of the land”, and the precedent it creates, taking into account the Court's historical deference to its own preference, should hold strong for many years, unless there are drastic changes in the regulatory environment within the European Union.

At a time of financial turmoil, when Member States attempt to cut costs across the board, while still attempting to salvage their ability to provide pharmaceutical products at affordable prices to their citizens, such drastic changes are not outside the realm of possibility. Until any such changes take place, however, low price Member States will have to come up with ways of addressing the issues raised by parallel trade, and dominant pharmaceutical firms will need to take care in how they attempt to apply supply quotas to low price markets. While doing so will not necessarily result in an agreement under Article 101 TFEU, it is possible to result in a finding of abuse of dominance under Article 102 TFEU.

Time will tell what balance will in the future be struck between the need to keep health care costs low, achieve universal coverage, protect intellectual property rights, and maintain the structural integrity of the single market. It should be no surprise that, when people's health is at stake, any choices made will not be easy.