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# Parallel Trade in Pharmaceuticals

## Legal confusion over competition and innovation

Parallel trade has been lawful in the European Union for over three decades. The established legal position is that it promotes the development of the single market and encourages intra-brand competition. Recently the European courts have wavered from this position with two Advocate Generals (AGs) disagreeing in the *Syfait* cases. But with neither view yet endorsed by the higher Courts, and the *GSK* decision which has upset matters further on appeal, the legal position is highly uncertain. Here we consider the core economic and legal issues, and the evidence

### The key issues

The legal and competitive differences surrounding parallel trade in patented medicines revolve around two issues – the benefits of competition, and its impact on pharmaceutical research and development (R&D).

Parallel trade is supported by the European Commission because it provides intra-brand competition. Competition in patented medicines is highly constrained because the manufacturer is the only entity able to supply them. This has led to widespread price controls usually through negotiations between public health bodies (as the regulator or monopsony buyer) and the pharmaceutical manufacturers. This reflects the view that patented medicine prices would otherwise be excessive and based on ability to pay rather than a reasonable return on costs. AG Jacobs in *Syfait I* (whose opinion was not considered or endorsed by the Court) argued that there were limited benefits from intra-brand competition where price controls prevented the operation of normal market forces.

The court in *GSK* considered whether a dual pricing scheme, where a higher price is charged for exported medicines than those for domestic consumption, was a restriction of competition. The court ruled that the 'object' and 'effect' of the scheme was to restrict competition under Article 81(1). But it annulled the European Commission's decision in *GlaxoWellcome* on the disputed grounds that it had failed to assess GSK's claims that restricting parallel imports would lead to greater global R&D, and hence qualify for exemption under Article 81(3).

### Are there consumer benefits?

The protection given by the patent system allows pharmaceutical manufacturers to control the prices, supply, and distribution of their patented medicines. This leads to significant price differences for the same medicine across Europe based on local market and regulatory conditions. This system of differential prices provides the incentive for parallel importers which, if the differentials are significant, can reduce domestic sales and prices in high priced countries. In *SyfaitI* AG Jacobs concluded that the benefits from intra-brand competition were small, and that parallel imports undermined national price controls.

This position was not endorsed by the court either in *Syfait I* or *GSK*. Indeed several empirical studies show that parallel imports do reduce the costs of medicines to health services, and the prices of patented medicines. Admittedly the magnitude of the taxpayer and consumer benefits differs considerably, and has been disputed. Also in contrast to AG Jacobs' Opinion, the prices of parallel imports are an important factor in price negotiations across Europe. Imported drug prices coupled with reference and cross-country price comparisons, are often an integral part of the price-setting process.

### The case for R&D

The bigger issue is whether parallel imports reduce pharmaceutical manufacturers' global R&D. The answer to this question begins with one fact about the facts – there is no evidence that parallel trade has reduced or otherwise adversely affected global R&D expenditure. This is surprising given that parallel trade in patented medicines has existed for over three decades in Europe.

Nonetheless the claim that parallel imports may reduce R&D must be given careful considered. It is based on a number of propositions or assumptions.

The first is that in order to (efficiently) recover R&D costs the pharmaceutical manufacturers must be able to charge different prices in different countries. This scheme of Ramsey prices (where technically prices are set in inverse relation to the price elasticity of demand) ensures that prices are set above marginal costs in a way that minimises distortions in consumption. Parallel trade undermines such a pricing scheme since it moves patented drugs from countries where they are cheap to those where they are more expensive. It thus serves to reduce average prices. This, it is argued, reduces the pharmaceutical manufacturers' gross profits, and because some studies show that higher gross profits are correlated with more global R&D, ergo parallel trade reduces R&D. Thus, argue the pharmaceutical manufacturers, there is an efficiency justification for restricting parallel imports.

Appealing as this analysis is, it nonetheless provides a highly simplified treatment of a very complex set of interactions. In particular it implicitly assumes that any set of prices levied by the pharmaceutical manufacturers is efficient, which is not the premise of the widespread controls on patented medicine prices. Mark-ups over marginal costs, even very high ones, can be efficient but they can also be excessive, containing monopoly rents.

## R&D in the real world

The above view also ignores the 'legal and economic' context in which parallel trade takes place within the EU. When these are taken into account, and government and pharmaceutical manufacturers are allowed to influence and react to both parallel trade and price controls, the picture is very different.

Consider first the alleged link between parallel imports and gross profits. This would seem a relatively uncontroversial conclusion. But it is not, at least according to recent economic theory, necessarily correct.

Two recent models developed by academic economists suggest that parallel trade can increase manufacturers' profits. This is because parallel imports may extend the global reach of patented goods and increase global profits. This can happen where parallel imports generate sales to a new group of consumers less concerned about the manufacturer's warranty and service provision. If this group is relatively large, then parallel imports tap into otherwise unexploited demand and raise gross profits.

In another model parallel imports can also increase sales and gross profits where the manufacturer's distributors face uncertain demand and periods of high inventories. Under some conditions allowing parallel imports reduces the risk of high inventories and thereby increases the effective demand for the manufacturers' products, and hence manufacturers' gross profits.

Other economic models deal directly with the link between parallel imports and R&D. These are based on complex game theory which takes into account the interaction between price controls, government and manufacturer behaviour. They show, again counter intuitively, that there are circumstances where parallel imports can actually increase R&D even when there is price regulation. For example Grossman and Lai's model shows that where governments are aware that lower prices may reduce availability of patented medicines and R&D, this will influence there negotiations over prices. The model indicates that parallel imports can result in higher average regulated prices compared to situations where there are no parallel imports as Governments seek to avoid these adverse supply-side effects. Even models which suggest that parallel imports reduce innovation identify extensions to the basic model where parallel imports increase R&D.

## Conclusions

While there is no reason to uncritically accept the conclusions of any of these models, they do sound a cautionary note of jurisprudential significance. It is that even in economic theory there is no certain relationship, and certainly not a presumed causal one, between parallel imports on the one hand, and pharmaceutical manufacturers' gross profits and R&D on the other. And, as has already been pointed out, there is no evidence that parallel trade in the EU has been linked to any measurable impact on global R&D.



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