

# CRA Competition Memo



## Parallel Trade in Pharmaceuticals: more harm than good?\*

The pharmaceutical sector has been at the centre of a number of recent controversies in EU competition law, not least the tension between the Commission's desire to encourage trade among member states to create a common market and the fact that parallel trade may undermine attempts by some national governments to reward and encourage investments in R&D.

Should research-based companies be allowed to take steps which might restrict the ability of parallel importers to reduce price disparities between Member States? Or should the Commission's goal of seamless cross-border trade take precedence? Research-based pharmaceutical companies have been struggling with this issue for some time, with the need to recover the common fixed costs of R&D underpinning their preference for the maintenance of price disparities. The Commission has often asserted the need for the encouragement of parallel trade to be the over-riding consideration. However, there are grounds for arguing that it is time for a rethink.

Such a view is based on the CFI's judgment in the *Glaxo* case ("*GSK DP*")<sup>1</sup>, currently subject to the outcome of an appeal to the ECJ, and is supported by recent work we have undertaken for pharmaceutical companies on this issue which incorporates the new additions to the economic literature on the subject. Our work suggests that there is a strong case for arguing that restrictions on pharmaceutical parallel trade are likely to bring net benefits to European consumers.

### The analytical framework for assessing restrictions on pharmaceutical parallel trade

The battleground between the Commission and research-based pharmaceutical companies on the issue of parallel trade is Article 81. Following the CFI in *GSK DP* many commentators believe that a dual pricing scheme<sup>2</sup> introduced by a pharmaceutical company in the EU would be found to have the effect of limiting parallel trade and that it would thereby be prohibited by Article 81(1) unless it is exempted under Article 81(3). This means that one must analyse whether or not the proposed scheme satisfies the four criteria for exemption under Article 81(3). Broadly speaking, Article 81(3) in the present context requires a balancing assessment of the adverse impact on *intra-brand* competition of a restriction on parallel trade (i.e. price competition between different distributors for the sale of the same product to customers in importing countries)

\* The authors of this note, Andrea Coscelli, Geoff Edwards and Alan Overd, have advised research-based pharmaceutical companies on these issues. The views expressed in this memo are those of the authors alone.

<sup>1</sup> Case T-168/01, *GlaxoSmithKline Services Unlimited v Commission of the European Communities*, Judgment of the Court of First Instance, 27 September 2006.

<sup>2</sup> A dual pricing scheme is a scheme whereby the manufacturer charges low prices to the wholesaler only if the product is sold to pharmacies in the "low price" country. High prices would apply to all other sales thereby severely restricting or eliminating altogether the wholesaler's ability to resell the product to pharmacies or hospitals in "high price" countries.

against the beneficial effects on *inter-brand* competition (i.e. competition between prescription drugs made by different pharmaceutical manufacturers, which is driven by innovation). As Article 81(3) requires that a "fair share" of the beneficial efficiency effects be enjoyed by consumers, the balancing assessment may be approximated by an analysis of the net effect of the restriction on consumer welfare.

Parallel trade in pharmaceuticals affects consumer welfare in three main ways. First, consumers in importing countries may face lower prices to the extent that traders pass on some of the cross-country price differentials and to the extent that parallel imports constrain prices of domestic supplies. Second, consumers in all countries may experience a long term decline in the supply and consumption of new drugs due to reduced incentives of pharmaceutical manufacturers to invest in R&D. Third, consumers particularly in exporting ("low price") countries may experience higher prices or, alternatively, delays in the launch of new products, and greater instability in supply. As noted above, to evaluate whether a restriction on parallel trade should be exempted under Article 81(3) it is necessary to evaluate each of these three effects to determine the net effect on consumer welfare.

### Evidence from the economic literature

A review of the economic literature on these issues finds support for the following five propositions relating to the assessment of the net effect of pharmaceutical parallel trade restrictions on consumer welfare described above. While the precise magnitude of the effects will obviously need to be estimated in specific cases, the direction of the effects is well-established.

- *Proposition 1: Parallel trade benefits consumers in importing countries through lower prices.*

Parallel trade has the potential to reduce the prices paid for pharmaceuticals in importing countries. There are two possible effects. First, parallel imports are likely to be cheaper than domestic supplies. Second, competition from parallel imports may cause prices for the domestic products (and substitute products) to be lower.

- *Proposition 2: Parallel trade leads to lower profits for manufacturers.*

A corollary of proposition 1 is that as consumers benefit from lower prices, manufacturers' profits will be lower. Indeed, since demand for prescription pharmaceuticals is typically assumed to be inelastic and as parallel trade is essentially a pure arbitrage operation that adds little or no value in the supply chain, the loss to manufacturers due to parallel trade will be equal to the sum of the benefits to consumers and the benefits to the parallel import supply chain (parallel traders, wholesalers and pharmacists). This means that any individual assessment will always find a

loss to the pharmaceutical companies that exceeds in magnitude the gains made by consumers in the form of lower prices.

- *Proposition 3: R&D spending depends on current and expected future manufacturer profits and as parallel trade lowers profits for manufacturers, parallel trade will likely lead to lower R&D spending.*

A wealth of literature links pharmaceutical R&D spending to both current and future expected profits. Current profits are an important determinant of pharmaceutical R&D because the uncertainty associated with pharmaceutical investments means that external financing is typically available only at a significant premium. Expected future profits are important as it is the expectation of future returns that spurs pharmaceutical manufacturers to make R&D investments. The extent to which lower profits translate into lower R&D spend will differ across companies and will be one of the key empirical issues to analyse in any specific case, but the empirical economic literature strongly suggests that lower profits lead to reduced R&D spending.

- *Proposition 4: Lower R&D spending will reduce the rate of innovation in pharmaceuticals and the development of new drugs, denying consumers long term health benefits.*

Recent research in health economics has enabled quantification of the long term loss to consumers from a reduction in innovation caused by a reduction in R&D spend. This research has found that reductions in R&D spend are likely to lead to significant reductions in consumer welfare. Moreover, this effect is likely to be significantly larger than all the other effects of pharmaceutical parallel trade, thereby driving the final result of the Article 81(3) balancing assessment.

A simple numerical example can help to explain. Assume, conservatively, that the profits of a pharmaceutical manufacturer are lower in a given year by the amount that consumers in importing countries gain from parallel imports (this ignores the fact that parallel traders will also appropriate some of the manufacturer's profits). Suppose the manufacturer's sales (and profits) fall correspondingly, by €50 million. Assuming a strong link between the manufacturer's sales (and profits) and R&D spending, and since pharmaceutical R&D spending typically represents around 15% of sales in any year, we assume that R&D spending is €7.5 million lower than it would be in the absence of parallel trade.

Taking a conservative estimate based on Lichtenberg's (2004)<sup>3</sup> paper that on average around €1,000 in pharmaceutical R&D expenditure produces one additional life-year,<sup>4</sup> the impact of parallel imports on the company's R&D budget comes potentially at the expense of 7,500 life-years. On the basis that one life-year is worth approximately €75,000 (a conservative figure based on a review of the economic literature on the value of life-years),

<sup>3</sup> Frank R. Lichtenberg (2004), "Sources of U.S. Longevity Increase, 1960-2001," 44(3) *Quarterly Review of Economics and Finance* 369-389.

<sup>4</sup> This finding has been relied upon by a number of subsequent studies as a measure of the productivity of pharmaceutical R&D investments.

the cost to consumers from parallel trade in the products of this company would be more than €500 million.

These estimated future costs to consumers are an order of magnitude larger than the immediate gains to consumers assumed in our example (€50 million). However, it should be noted that whereas these immediate gains to consumers are certain, the estimated future costs are not, and they should be appropriately discounted. Other caveats apply. First, one must accept the proposition that a fall in pharmaceutical manufacturer profits will translate into a fall in R&D spending (i.e. proposition 3). Second, one must accept the proposition that lower R&D spending will translate into fewer new drugs (i.e. proposition 4). Third, the result is affected by the link between R&D spending and life years derived from the economic literature.

Nonetheless, the illustration demonstrates the potential for parallel trade to deny consumers substantial long term benefits.

- *Proposition 5: Parallel trade also harms consumers particularly in exporting countries by contributing to delays in supply of new products and instabilities in the supply chain.*

Delays occur because pharmaceutical manufacturers are reticent to launch in low price countries when parallel trade will divert some of the supply to undermine prices in high price countries. Instabilities arise when supplies meant for domestic consumption in the exporting country are diverted by parallel traders to high price countries. Though its magnitude will vary across cases, the direction of this effect is clear and it strengthens the result that restrictions on parallel trade are likely to enhance consumer welfare.

## Conclusion

In the pharmaceutical industry, price differentials between countries can be interpreted as a reflection of the different willingness of the various governments to pay for the common fixed costs of pharmaceutical R&D, rather than any differences in variable production costs. As such, these price differentials reflect the outcome of a complicated bargaining process between manufacturers and governments addressing the problem of how to recover R&D costs across a number of separate markets. This means the usual arguments in favour of free trade to eliminate these price differentials do not apply.

Pharmaceutical parallel trade undermines this approach and jeopardises investments in pharmaceutical R&D. While this trade undeniably offers immediate benefits to consumers in importing countries in the form of lower prices, the recent economic literature suggests that the (albeit uncertain) long term costs for consumers in all countries, in terms of foregone pharmaceutical innovation and corresponding health benefits, are likely to outweigh the short term gains. Such a finding should be a central part of an assessment of restrictions of parallel trade by pharmaceutical companies under Article 81(3).

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