

# The application of Art.81 to the Pharmaceutical sector: where are we after the CFI Judgment in the GSK case?



INTERNATIONAL

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## **Art. 81 in the Pharma sector – where are we?**

- **CFI Judgment in the GSK case (September 2006) and Advocate General Jacob's Opinion in the Syfait case (October 2004) seem to indicate that the Commission must consider more carefully a number of arguments made by pharma companies to justify differential pricing across the EU and seem to indicate that a “balancing exercise” needs to be carried out**
- **Both GSK and the Commission have appealed the CFI Judgment so the ECJ will now address this issue**
- **What are the key “factors” to consider in the balancing exercise under Art. 81(3)? (Application of Art. 81(3) to parallel trade is very specific to the pharma industry.)**

# General agreement on the theoretical framework

- **Main effects of parallel trade in prescription drugs in the EU given the current regulatory framework that leads to different pricing across the EU:**
  - Consumers (patients and payers) in importing countries gain from parallel trade (*direct effects* – lower prices of the imported drugs & *indirect effects* – price reductions in the importing countries) [+]
  - Consumers in exporting countries might be harmed if new drugs are introduced with delays and/or prices are higher than they would be absent parallel trade [-]
  - Revenues (and profits) for the pharma companies are reduced [neutral]
  - Lower revenues for the pharma companies might lead to lower R&D spend (not accepted by the Commission in GSK) [neutral]
  - Lower R&D spend *might* lead to less innovation which leads to consumer harm (dynamic story) [-?]

# Propositions to be tested empirically: economic literature & internal evidence

## 1. Patient/payers in importing countries benefit from lower prices brought by parallel trade: *direct* and *indirect* effects

- ✓ The existence of this effect seems clear – the interesting question is its magnitude.
- ✓ Several attempts to quantify this effect
  - ✓ “York study” (2003)
  - ✓ “LSE Health” study (2004)
  - ✓ CAST study (2006)
- ✓ Differences in results from these studies derive from the different time periods used for the analysis, different countries covered and different assumptions used to deal with data limitations.
- ✓ Analysis using the internal evidence for a specific company. Internal documents might also indicate whether a company reduced the “domestic” price of some products because of parallel imports.

# Propositions to be tested empirically: economic literature & internal evidence

## 2. Parallel imports lead to lower revenues and profits for the pharma companies (compared to a world with no parallel trade)


- ✓ The existence of this effect seems clear – the interesting question is its magnitude.
- ✓ “LSE Health” study (2004)
- ✓ CAST study (2006)
- ✓ Internal and direct evidence for a specific company (What time period? All products? All countries?)

## Propositions to be tested empirically: economic literature & internal evidence

### 3. Part of the economic loss to the pharma companies goes to the parallel traders

- ✓ The existence of this effect seems clear – the interesting question is its magnitude.
- ✓ Quantification? (What countries? Time period? Assumptions?)
- ✓ Is it “wastage” or should we include the margins of the traders in the welfare measure we use (as the Commission seems to imply)?

## Propositions to be tested empirically: economic literature & internal evidence

 **Parallel trade harms patients in “exporting” countries by generating delays in the introduction of new products and instabilities in supply (and causes extra costs to the companies because of the increased sales volatility)**

- ✓ The existence of this effect seems clear – the interesting question is its magnitude.
- ✓ Edmonds, Glyn et al (2000) – EU countries experiencing the most severe delays include some of the exporting countries. Causality or simple correlation?
- ✓ Danzon, Wang and Wang (2005) find a similar effect
- ✓ Internal evidence for the specific company

## Propositions to be tested empirically: economic literature & internal evidence

### 5. R&D spending depends on current profits (or revenues) so lower profits lead to lower R&D spend

- ✓ The existence of this effect is somewhat controversial as one would need to rely on a failure of capital markets theory (see Lichtenberg (2001))
- ✓ Extensive evidence in the empirical literature (Grabowski and Vernon and others) from reduced-form regressions where R&D spend is affected by measures of cash flows (and earnings)
- ✓ Probative value of internal evidence about decision-making processes, budgetary decisions and the effect that changes in current revenues (and profits) have on actual R&D spend?



## Propositions to be tested empirically: economic literature & internal evidence

### R&D spending depends on expected profits

- ✓ The existence of this effect seems clear – the key question is its magnitude.
- ✓ Internal documents are key here – effect on future profits is clear if R&D projects receive periodic (go ahead/don't go ahead) reviews where an estimate of future revenues plays a key role in the decision
- ✓ It is puzzling why the Commission did not seem to accept the causality of this link in its 2001 GSK decision. (Whilst the magnitude can be obviously subject to debate.)

# Propositions to be tested empirically: economic literature & internal evidence

## 7. Greater R&D spend from current level leads to more innovation (and greater consumer benefits)

- ✓ The existence (and importance) of this effect is also somewhat controversial
- ✓ General papers about under-investment because private rate of returns are lower than social rates of return (Arrow; Mansfield et others)
- ✓ Grabowski and Vernon – work on returns to pharma R&D
- ✓ Jensen (1987) – positive correlation between R&D expenditure and drug discovery
- ✓ Internal evidence on the internal hurdle rate for projects and internal discussions about the expected return from “marginal “ projects that are not implemented

## Conclusions – a few unresolved issues

- **Debate in front of the ECJ will be on the 2001 Commission decision in GSK where some of the arguments discussed here were only partially presented/discussed**
- **Will the ECJ decision be the final word on this issue?**
- **What should companies do in the meantime?**
- **A significant proportion of the empirical results derive from general studies.**
  - To what extent can a company rely on general results and to what extent would a company be expected to carry out its own internal assessment?
  - Should the assessment be based exclusively on historic data or should one also attempt to model the effect on future behaviour?