Pharmaceuticals and competition: Evolution and Revolution?

Seminar for Members of the Judiciary of Malta

1 March 2007

Nadia de Souza – DG Competition
European Commission

views expressed are personal

Introduction

- The Commission's long standing competition policy has been to fight against attempts by research based pharmaceuticals companies to restrict parallel trade.
- The rationale for the Commission's approach:
  - Single Market in pharmaceuticals requires the unhindered free movement of products - private companies cannot erect barriers to undermine this without distorting intra-brand competition
  - The efficiency claims advanced by the research based pharmaceutical industry is unsubstantiated – i.e. there is no evidence that partitioning the common market would spur global investment in inter- brand innovation
- This has been challenged/undermined in recent years by the European courts.

The Bayer Agreement

- First in October 2000 in Case T-41/96 the CFI annulled a Commission decision addressed to Bayer.
- Bayer ceased fulfilling increasingly large orders by wholesalers in France and Spain for “Adalat” destined for the UK.
- The Commission considered this to be an export prohibition agreed “as part of their ongoing business relations” between Bayer and the wholesalers.
- The CFI found that the Commission had not established that their was a “common intention” between Bayer and its wholesalers to justify the conclusion that there was an “agreement” falling within Article 81.

The Bayer agreement

- Since the ECJ confirmed the CFI’s judgment supply quota systems fall outside Article 81.
- But dual pricing schemes remain caught as “agreements” by Article 81.
- Ongoing debate on whether Article 82 might be used to catch supply quota systems.
- The jury is out on the applicability of Article 82 to supply quota systems.

The Syfait/GSK reference

- Next in Case C-53/03 the Greek Competition Authority referred questions of interpretation of Article 82 to the ECJ concerning the circumstances in which a dominant GlaxoSmithKline might refuse to fulfil orders from wholesalers in order to limit parallel trade in three products.
- The ECJ ruled in May 2005 that it had no jurisdiction.
- But, in October 2004, A-G Jacobs had considered that such a refusal could be justified in the current circumstances of the pharmaceuticals sector.

The Syfait/GSK reference

- These circumstances were:
  - price differentials between the Member States as a result of State intervention;
  - national obligations to ensure availability of stocks;
  - negative consequences of parallel trade for competition, the common market and innovation; and
  - the fact that consumers and public authorities may not necessarily benefit from parallel trade.

The Syfait/GSK reference

- It seems that we will now have another reference from Greece in identical terms in Cases C-468-478/06.
- So, the ECJ will get another opportunity to pronounce on the application of Article 82 to supply quota systems.
- Will A-G Jacobs' view prevail or not?

The GSK exemption

- Finally, in September 2006, in Case T-168/01, the CFI partially annulled a Commission decision regarding differentiated prices charged to Spanish wholesalers by GlaxoSmithKline for eight products.
- The Court accepted that there was an anticompetitive agreement.
- However, it considered that the Commission had not properly examined the loss of efficiency (capacity to innovate) associated with parallel trade, nor the gain in efficiency enabled by differentiated prices.
- It therefore annulled the Commission's rejection of a request for an exemption under Article 81(3).

The GSK exemption

- All parties to the CFI's GSK judgment have appealed the judgment to the ECJ - guaranteed to raise interest of ECJ to look into the case closely!
- So, the ECJ will get the opportunity to pronounce on the application of Article 81 to dual pricing schemes at the same time as it is being asked to rule on the application of Article 82 to supply quota systems.
- Excellent timing!

The way ahead

- Clearly the venue for debating the parallel import question today is the ECJ, where two test cases are pending.
- Meanwhile, DG COMP's enforcement priorities have been re-oriented to deal with inter-brand competition between innovative products and between such products and their generic equivalents.

The way ahead cont'd

- This re-orientation aims to develop the experience acquired in the *AstraZeneca* case to tackle different types of life cycle management strategies by research based pharmaceutical companies aimed at raising rivals' entry barriers.

The way ahead cont'd

The *AstraZeneca* decision
15 June 2005
(available on:
http://ec.europa.eu/competition/antitrust/cases/decisions/37507/en.pdf)

Case T-321/05 ***AstraZeneca AB & AstraZeneca plc v Commission***, (2005/C 271/47)
(summary available on:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:C2005/271/47:EN:NOT)