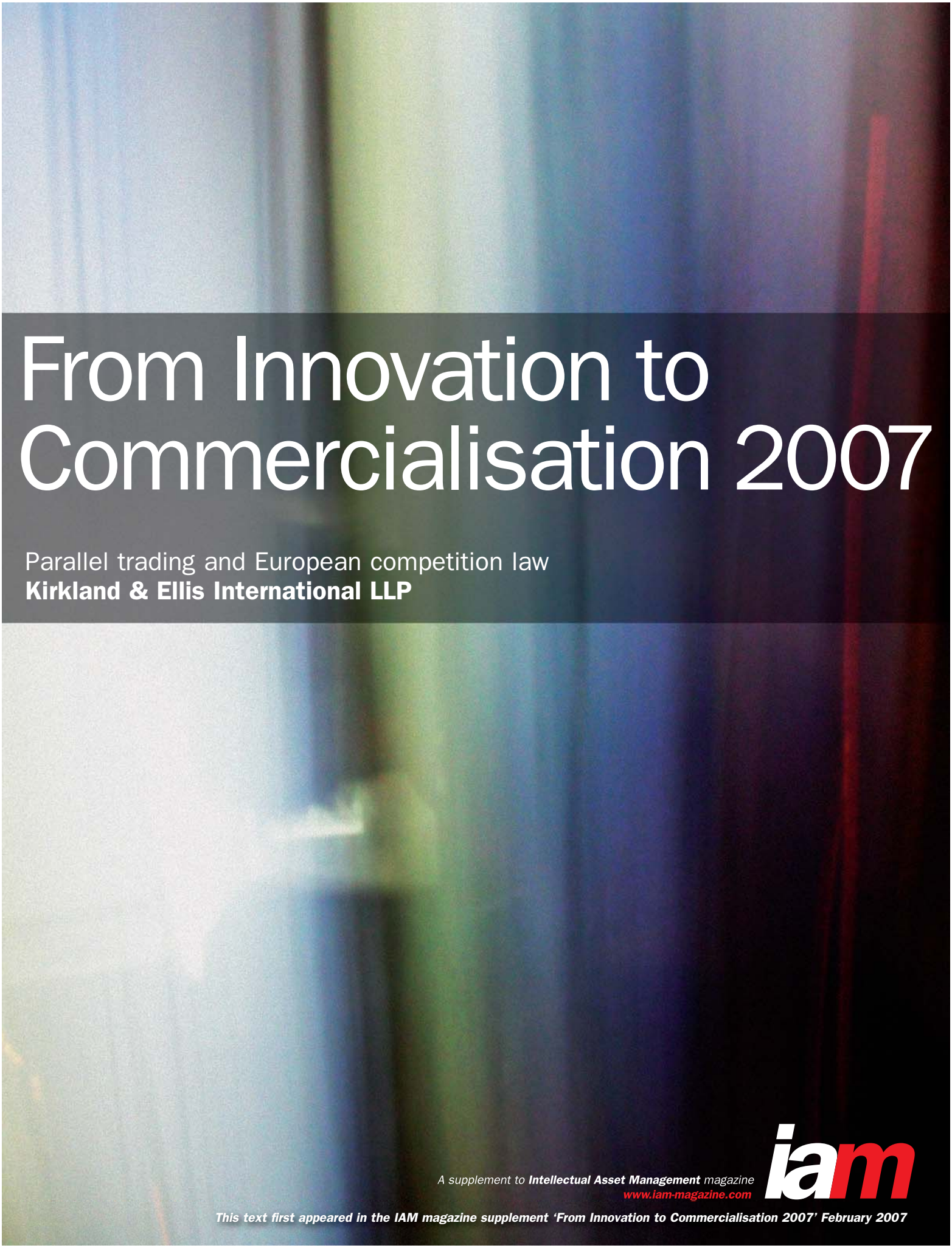

# From Innovation to Commercialisation 2007

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**Kirkland & Ellis International LLP**

*A supplement to* ***Intellectual Asset Management*** *magazine*
***www.iam-magazine.com***

***This text first appeared in the IAM magazine supplement 'From Innovation to Commercialisation 2007' February 2007***

# Parallel trading and European competition law

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One of the issues of greatest concern to the pharmaceutical and biotechnology industries in Europe is that of parallel trading and the ability of manufacturers to control this trading by contractual and other means. The reasons for the boom in parallel trading in pharmaceuticals in the European Union are easy to understand – most prescription drugs are subject to significant price differences between member states as they are paid for by national health or insurance schemes, effectively creating different markets within what is supposed to be a single market. Over the years, this issue has led to a substantial amount of litigation. While the European Commission has generally been adverse to many practices of the pharmaceutical industry, the European Court of First Instance (CFI) and the European Court of Justice (ECJ) have, with their decisions in the *Bayer* case (2000), the *Syfait* case (2005) and the *GlaxoSmithKline* (GSK) case (2006), supported some of the industry's attempts to reduce parallel trading, acknowledging that the particular conditions of the pharmaceutical industry need to be recognised when applying European competition law. The underlying question in these three cases was the extent to which manufacturers may, in contractual arrangements with their licensees or distributors, impose restrictions which will give manufacturers greater control over parallel trading.

## Background

Article 81(1) of the Treaty of Rome (the Treaty), which established the European Union, prohibits any agreement, decision or concerted practice between parties which has as its object or effect the restriction of competition to an appreciable extent between member states in the European Union. Distribution and licence agreements that have an impact on trade in the European Union will be measured against Article 81(1). Article 81(3) of the Treaty provides an exception to Article 81(1): if it can be proven that an agreement, decision or practice which breaches Article 81(1) nonetheless contributes to improving the production of goods or economic progress while allowing consumers a fair share of the resulting benefit, without affording the parties the possibility of eliminating competition in respect of the products in question, then the agreement, decision or practice cannot be considered in breach of Article 81(1). Furthermore, Article 82 of the Treaty prohibits any company in a dominant position from taking any action which results in an abuse of its dominant position.

## The *Bayer* and *Syfait* cases

In the *Bayer* case, the CFI held that the Bayer group's practice of ceasing to fill increasingly large orders placed by wholesalers of its cardiovascular drug Adalat in Spain and France with its Spanish and French subsidiaries did not amount to a concerted practice in breach of Article 81(1). Between 1989 and 1993, the prices of Adalat fixed by the Spanish and French health services were on average 40% lower than prices in the United Kingdom. Because of these price differences, wholesalers in Spain and France exported Adalat to the United Kingdom, with Adalat sales by Bayer's British subsidiary falling by almost 50% as a result of these parallel imports. The CFI found that Bayer's decision to cease filling these orders had been unilateral and that its distributors had not participated in the decision. As such, there was no concerted practice to restrict competition.

The *Syfait* case was decided on a jurisdictional issue and left open the

question as to whether the manufacturer's practice of limiting wholesaler supplies to what wholesalers actually needed for their domestic market amounted to abuse of a dominant position under Article 82 of the Treaty. However, the Advocate General (who provides opinions to the ECJ which are often highly regarded) concluded that such restrictions do not necessarily constitute an abuse of a dominant position, even if the intention is to curtail parallel trading. The Advocate General held that particular circumstances in the pharmaceutical industry justified such conduct. This line of thinking is further reflected in the ECJ's more recent decision in the *GSK* case.

### The *GSK* case and recognition of the particularities of the market

In the *GSK* case, the CFI examined GSK's double pricing practices embodied in its written conditions of sale with its Spanish wholesalers. The conditions of sale required Spanish wholesalers to pay higher prices for products which they exported outside Spain than for products resold for consumption on the domestic market.

As in the *Bayer* case, GSK was concerned about differences in the prices of its drugs on the Spanish and UK markets, in particular with respect to certain of its anti-allergy, anti-asthma, anti-epileptic and anti-migraine drugs. The vast majority of Spanish wholesalers agreed to GSK's conditions of sale. However, the European Commission received complaints from a number of trade associations about GSK's practices. As a result of these complaints, the European Commission formally prohibited GSK from maintaining a dual pricing scheme in Spain, finding that the conditions of sale constituted an agreement restricting competition in breach of Article 81(1) of the Treaty. GSK appealed this decision to the CFI.

The CFI concluded that the conditions of sale did not have as their main purpose the restriction of competition based on the provision for differentiated prices arising from parallel trading. The CFI considered that, given the unique characteristics of the pharmaceutical industry, the normal rule that a restriction on parallel trading always has as its object the restriction of competition cannot be presumed without further consideration of this legal and economic context.

In particular, the CFI concluded that the European Commission had not taken proper account of the special nature of the pharmaceutical sector. Unlike in other economic areas, the prices of medicines reimbursed by national health authorities are not fully determined by the rules of supply and demand, but are rather controlled by member states. For this reason, it cannot be presumed that parallel trading tends to reduce prices and thus increase consumers' welfare. However, the CFI concluded that the conditions of sale could nonetheless have as their effect the restriction of competition, given that parallel trading permits a limited but real reduction in the price of medicines. Insofar as they hindered that advantage, the conditions of sale could diminish the welfare of end consumers and, as such, be in breach of Article 81(1) of the Treaty.

GSK mounted a defence based on Article 81(3) of the Treaty, focusing on an efficiency theory centring on the role and benefits of research and development. GSK argued that:

- Parallel trading would lead to a loss in efficiency by reducing its capacity to innovate; in contrast, the conditions of sale would bring about a gain in efficiency by enabling it to increase its capacity for innovation.
- The conditions of sale would contribute to improving the distribution of medicines by limiting parallel trading, which results in delay in products reaching the market in certain member states and to less-than-optimum allocation of the medicines GSK offers for sale.
- A fair share of the benefits attached to the conditions of sale would be reserved for end consumers.

To support this efficiency theory, a number of peculiarities of the pharmaceutical industry had to be considered:

- The pharmaceutical sector is characterised by competition through innovation. R&D is costly and risky. Manufacturers can differentiate their income by adapting the prices of medicines to the preferences of end consumers, where those preferences differ. Price differentiation allows the cost of R&D to be recovered from those end consumers who are prepared to pay for it.
- Most medicines are protected by patents and the schemes operated by the national health authorities impact on pricing. As a result, the R&D costs that manufacturers can recover will vary from member state to member state.
- Parallel trading has the effect of reducing income to an uncertain, but real, degree. This practice of "free riding" is characterised by the fact that the

intermediary (ie, the distributor or wholesaler) steps out of the role which it traditionally plays in the value chain and instead becomes an arbitrageur, obtaining a greater share of the profit. This activity creates no specific added value or benefit for the end consumer.

- GSK's conditions of sale sought to optimise income and neutralise parallel trade. They simply restricted the possibility to sell, outside Spain, medicines bought at the price set with a view to reimbursement by the Spanish national health authorities, while allowing sales in other member states to be made at the prices set with a view to reimbursement by the local national health authorities. While GSK would retain the resulting profit, this was pro-competitive as GSK would have an incentive to reinvest at least part of its surplus profits in further R&D.

The CFI concluded that the European Commission had failed to consider GSK's arguments with respect to the specific characteristics of the pharmaceutical market and returned the issue for further examination by the Commission.

## The outlook

While the basis for European competition law remains that of free trade between member states, it is difficult to concede that, when it comes to pharmaceutical products, the European Union represents a single market in real economic terms, as distortion is created by the price regulations in each member state. Clear economic arguments can thus be made to distinguish the pharmaceutical industry from other sectors.

The CFI's recent decision in the *GSK* case, together with the earlier statements in the *Bayer* and *Syfait* cases, supports the industry's argument that special consideration should be given to the specific conditions of the pharmaceutical industry when applying European competition law. It appears that, if properly supported by the right evidence, many industry practices may be successfully defended, allowing the pharmaceutical industry to continue its efforts to restrict the impact of parallel trading in the European Union.

The issue is set to remain at the forefront of judicial activity at the European level. In January 2007, a Greek court filed 11 references with the ECJ asking it to rule on a variety of issues, including:

- Whether GSK's refusal to fill orders amounts to an abuse under Article 82 of the Treaty.
- Whether the answer to this question should be affected by the particular economic conditions of the pharmaceutical market.
- Whether national competition authorities must apply European competition law in the same way to markets which function competitively as to those in which competition is distorted by state intervention, such as the pharmaceutical market.

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