

Sidestepping the Issue

The latest European Court ruling fails to resolve parallel trade uncertainty, reports Edward Miller of Reed Smith

The European Court of Justice has again refused to set down clear guidance on the legality of the refusal by pharma companies to fill export orders from parallel traders. The ongoing legal battle between drug wholesalers and pharma companies about restrictions on parallel trade enters a new phase of uncertainty following the most recent ruling by the European Court of Justice in a case brought against pharma giant GSK by a group of Greek wholesalers.

Parallel trade occurs when wholesalers take advantage of different reimbursement prices for the same drugs prevailing in different EU member states by buying drugs and shipping them from low price countries to high price countries.

The most recent ruling (itself in a case which has kept the parties in litigation for eight years already) is the latest episode in a continuing soap opera of cases zigzagging between national European courts and competition regulators, the European Commission and the European Court of Justice. Unfortunately, the implication of the ruling is that this particular series still has a long time to run.

In his earlier advisory opinion to the Court in this case, the European Advocate General had clearly not been impressed with the string of familiar arguments which GSK had dutifully trotted out. These are essentially that:

- ◆ Drug companies' refusal to supply parallel traders for export is justified by differential national reimbursement prices imposed on the drug companies by state social security authorities, rather than set by the drug companies
- ◆ Parallel trade unfairly impinges on a fair return on the substantial R&D required to bring a drug to market
- ◆ Restrictions on drug exports were needed to ensure adequacy of national supply in each country
- ◆ Parallel trade serves only to line the pockets of the parallel traders, rather than serving the interests of consumers

As expected, the European Court did not dissent from the views of its Advocate General. To do otherwise would have been to open up a new exception to the much promoted imperative of completing the European internal free market by vigorously attacking any obstacle placed in the way of inter-state trade. It would have taken a very brave court indeed to do this.

However, in a significant move toward the position advanced by the pharma companies, the Court held that pharma companies can refuse to supply 'unusual' orders from wholesalers. But, in order to prevent the drug companies from jumping to the conclusion that any export order at all could be 'unusual', the Court also made it clear that a refusal to supply based only on the fact that the order was for export rather than domestic sale would be unlawful. It was for the national courts to decide what was unusual in the light of previous 'regular commercial practice'.

The Court used two previous cases, both over 30 years old, as authority for this idea. One, admittedly, is one of the leading cases in the area of abusive refusal to supply. However, in a judgment in that case running to over 300 paragraphs, you need to look carefully to identify the two sentences the Court relied on in the GSK case. The other case cited by the court concerned a refusal to supply petrol in a fuel shortage, where it was held to be not abusive for BP to supply less fuel to an occasional customer than to a regular customer – hardly a compelling analogy to GSK's case.

One might speculate that the Court felt that it was caught between a rock and a hard place. The Court did not want to make the pharma industry – one of the most vibrant sectors in the EU – a new wide exception to its crusade to complete the internal market. However, perhaps a degree of sympathy for the fact that the national pricing differentials at the root of the problem are not the pharma companies' fault left the Court with a desire to leave the door ajar.

So where does this leave us? With about €4 billion of parallel trade annually, one might think that there is an awful lot of 'regular commercial practice' which parallel traders can use to justify their export orders. One might also ask whether it would still be normal commercial practice for a parallel trader to request an increase in supplies of 5, 10 or 20 per cent, measured over a month, a year, or perhaps the history of the trader's relationship with the relevant drug manufacturer. What about the case of a parallel trader who currently trades in one drug, but seeing differentials falling away, switches his request for supply to similar volumes of another drug manufactured by the same supplier? Such questions will all provide first rate opportunities to grow the practices of the drug companies' and parallel traders' lawyers.

The truth is that although pharma companies are likely to hail the judgment a major step forward, it may, in practice, be



difficult to convince national courts that large orders for export from existing traders are unusual within the meaning of the GSK judgment, given the already widespread nature of parallel trade. The judgment will, however, provide support to those national courts and competition authorities, such as the French Competition Council, who have shown sympathy with the more fundamental arguments raised by the pharma companies.

A likely reaction by pharma companies will be to pursue their existing progression down the supply chain. As the Courts continue to fail to resolve the uncertainty about how the law regulates drug distribution, pharma companies are likely to attempt to gain more security by acquiring more direct ownership and control of distribution. Even this, however, is not a complete answer. A refusal to supply a third party distributor can still be abusive, even where the supplier has established its own internal distribution system – particularly where the supplier was previously trading with the third party distributor. This difficulty for the drug companies may also then lead to a temptation to leverage the existing legal obligation to satisfy demand in each national market by canny planning of creation and utilisation of production capacity so as to ensure that in a given geography, available supply does not exceed local demand. So, we might see some cases where drug manufacturers argue that they simply do not have sufficient production capacity to be in a position to guarantee supply in

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Edward Miller is a partner at Reed Smith, London, specialising in international transactional work and UK and European competition, procurement and anti-trust regulation. He regularly advises companies in the pharma and life sciences industries on parallel trade, European distribution and pricing structures, UK and European merger control, and other UK and European anti-trust issues. Edward has successfully represented clients in a range of industries in investigations conducted by UK and European anti-trust authorities, multi jurisdictional mergers and regularly counsels clients on competition compliance. He also devises and delivers training on anti-trust issues at all levels from sales staff to senior management.

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the various EU member states, whilst at the same time feeding demand for export orders.

Overall, this case unfortunately looks like another piece of rather inelegant sidestepping of the key issue by the European Court. The result will be more litigation and more uncertainty in the market as to the permissible scope of parallel trade. In short – business as ‘usual’. ♦

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