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GC's Lundbeck ruling to affect GSK, Servier UK 'pay for delay' cases

PaRR Confirmed

- GSK, UK pay for delay cases may have factual, other differences but case templates echo Lundbeck
- Pharma originator's willingness to make substantial payments may show doubt of patent's validity
- English courts to deal with UK and EU competition law consistently on facts of each case

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The General Court's (GC) landmark ***Lundbeck*** ruling that 'pay for delay' settlements by pharmaceutical firms can amount to a restriction of competition by object, will impact current parallel English court cases, where fines by the UK competition authority are currently under appeal, three lawyers told *PaRR*.

On 8 September, the GC upheld the European Commission's (EC) decision and EUR 93.8m fine of Danish pharmaceutical company Lundbeck, and four generic rivals, for reverse settlement agreements in breach of Article 101 TFEU.

In 2002, Lundbeck agreed to pay **Merck KGaA/Generics UK, Arrow** and **Ranbaxy**, to delay market entry of cheaper, generic versions of popular antidepressant, Lundbeck's branded citalopram.

The English courts are hearing appeals of similar, recent 'pay for delay' infringement rulings. The Competition Appeal Tribunal (CAT) will shortly hear appeals by **GlaxoSmithKline PLC ("GSK"), Generics UK, Merck KGaA, Xellia, Alpharma** and **Actavis** against the Competition and Markets Authority's (CMA) recent total GBP 45m (EUR 57.8m) fines for agreeing to stall entry of cheaper generic antidepressant paroxetine, Seroxat.

The similarities and points of difference between Lundbeck and other UK pay for delay cases will have been "carefully pored over" by advisers in those appeals raising similar issues, a lawyer familiar with *Lundbeck* told *PaRR*.

There are many similarities between the GSK and *Lundbeck* cases, both being classic examples of originator pharma companies paying generic companies to delay entry with competing products, while arguing that the payments form part of legitimate settlements of patent infringement actions, Richard Pike, a competition partner at Constantine Cannon, told *PaRR*.

The CMA only investigated the GSK case as a result of a 'tip-off' from the EC, which "presumably occurred as part of the monitoring of patent settlements" following the EC's pharma sector inquiry; or, perhaps more likely, from its Lundbeck investigation, he said.

As in *Lundbeck*, GSK's basic patent had expired and all that was left were secondary or process patents.

While there are undoubtedly further factual differences, on which GSK's lawyers will surely focus, the basic template of the cases is pretty similar, Pike added.

The CMA, however, found that GSK's deals on paroxetine included an abuse of dominance aspect under Article 102, and a Chapter 1/Article 101 restrictive agreement, which the CMA chose to pursue. *Lundbeck* concerned a breach of Article 101 only.

Richard Eccles, a competition partner at Bird & Bird in London, told *PaRR* that regardless of this difference, "in each case, the company claimed its actions were valid protection of its IPR."

There were also some subjectively prejudicial internal statements in *Lundbeck* that appear to lack direct parallels in GSK, Pike said, referring for instance to "internal documents" suggesting Lundbeck did not really expect to be able to successfully defend its patents. There was reference to sharing dollars between themselves and the generics, Pike said, adding that it appears GSK staff were a little more circumspect.

In the paroxetine appeals, the lawyer close to the matter said the appellants also raised the relevance of the exclusion for vertical agreements, "which was particular to UK law at the relevant time". The Vertical Agreements Exclusion Order was unavailable to Lundbeck.

Moreover, the fact confirmed in the *Lundbeck* judgment that such conduct can potentially be dealt with as an 'object' infringement as a matter of law, does not preclude different arguments being argued on the facts, the lawyer said.

Impact on cases

The lawyers agreed the UK courts should follow aspects of *Lundbeck* in considering the appeals. Generally, the CAT is obliged to follow EU law unless it considers there are relevant differences.

The CAT must deal with questions arising in relation to UK and EU competition law in a manner that is consistent with the treatment by the EU institutions of corresponding questions arising in EU law.

Probably the most significant issue in all the 'pay for delay' cases is how the court is to treat the fact that the originator claimed to have a valid patent that prevented entry by generics, Pike told *PaRR*.

It can be argued that the court should treat the patent as valid unless and until it has been found otherwise and that, as such, there is no potential competition until the patent has lapsed or been found invalid, he added. This is not the view taken by the EC nor GC in *Lundbeck*, nor the CMA in GSK.

All have essentially taken the view that if there was any doubt about the patent's validity, that meant there was the potential for competition, Pike said.

The fact that the originator was willing to make substantial payments is sufficient to show that there was material doubt about the validity of the patent, he added.

The CAT would be obliged to follow that approach unless overturned by the CJEU in the interim or unless it decides to make a reference to the CJEU challenging that approach in the particular circumstances of this case.

The existence of potential competition needs to be answered on the facts of individual cases. Therefore, it cannot be excluded that the CAT might reach a different conclusion than the GC on the potentially different facts in the cases before it, the first lawyer said.

Pike was a little surprised that, as matters stand, the GSK final paroxetine hearing will occur before potential appeals to the CJEU of the Lundbeck GC judgment have been decided. The deadline for an appeal from the GC is next week. "I can only assume that the CAT has decided, up to now, that it is not practical to set the GSK appeal in aspic pending a final resolution of the Lundbeck case."

Impact on pharma firms

The CMA, in its GSK decision, has almost gone as far as to say it thinks there is public interest in all pharma patent claims being litigated to a conclusion rather than being settled at all, Pike said.

It will be important, however, to ensure that settlement terms have a clear and defensible link to the pending dispute, he said. One of the big issues for GSK is "that there is an apparent disconnect between the settlement terms and the disputes that were pending."

"It does not look like the parties reached a middle position between their two competing positions in the litigation but rather that they did an entirely separate commercial deal that could only be justified by extraneous, arguably anti-competitive factors," Pike said.

UK health ministers' claims seeking to recover NHS losses from French drugmaker **Servier** based on an EC ruling, under appeal in Europe, should also be affected.

The CMA is continuing its two current pharma sector investigations, announced in March 2016, on which *Lundbeck* would also have an impact.

Given the GSK appeals are now being case managed, there has been time for the CMA to use the *Lundbeck* judgment against the appeal of its decision - in its skeleton argument, Eccles said, and at the hearing of the appeal in February.

GSK did not reply to a request for comment.

by Miriam Kenner in London

- Companies
  - · GlaxoSmithKline Plc
  - · Actavis Group hf
  - · Alpharma, Inc.
  - · Merck KGaA
  - · Norton Healthcare, Inc.
  - · National Health Service
  - · Generics [UK] Limited

  Agencies
  - · UK Competition and Markets Authority
- CASE Files
  - EU investigation into pay-for-delay arrangements involving Citalopram (2010)
  - EU investigation into pay-for-delay arrangements by Lundbeck involving Citalopram (2010)
  - UK investigation into pay-for-delay arrangements by GlaxoSmithKline involving paroxetine (2011)
  - UK private litigation by British health authorities concerning Servier pay-for delay agreement (2011)