CASE COMMENTS

THE CAT'S LATEST PAROXETINE 'PAY-FOR-DELAY' JUDGMENT: MARKET DEFINITION CONFUSION

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The 10 May 2021 supplementary judgment of the Competition Appeal Tribunal (CAT) in the *Paroxetine* case upholds the EU approach to so-called 'pay-for-delay' patent settlements as well as confirming the 2016 infringement decision reached by the Competition and Markets Authority (CMA). It also reduces the fines imposed on the parties.

However, the main point of interest may be the unusual approach the judgment adopts to market definition. It seems that the only way to make sense of the judgment on this point is to recognise that the CAT is adopting a different legal test to determine the relevant market before and after the point at which generic competitors are preparing to enter the market. In the view of the authors, that makes little legal or economic sense. It does, however, allow the CAT to respect EU case law while upholding the original decision of the CMA. In effect, a questionable approach to patent settlements seems to have led to a questionable approach to market definition.

Background

In 2016, the CMA found that GlaxoSmithKline (GSK) and Alpharma Limited and Generics (UK) Limited ('the generics') had breached EU and UK competition law by entering into a series of agreements that delayed entry of the anti-depressant drug, paroxetine. The relevant agreements, which dated back to 2001, settled litigation relating to patents held by GSK in relation to paroxetine. In exchange for payments and other value transfers worth over £50 million, the generics agreed not to supply paroxetine in the United Kingdom before 2004.

In March 2018, the CAT issued an interim judgment largely dismissing the appeals from GSK and the generics against the CMA's findings. At the same time, the CAT referred certain questions to the European Court of Justice (CJEU) for a preliminary ruling on the application of EU law. The CAT deferred its final ruling pending the response of the CJEU.

In a January 2020 preliminary ruling, the CJEU confirmed that this type of settlement agreement may constitute both (i) a 'by object' infringement of competition rules (requiring no proof of any effect on competition), and (ii) an abuse of dominance by the patent holder.

The CAT Judgment

The CAT judgment dismisses all of the substantive grounds of appeal against the CMA decision, while at the same time reducing certain aspects of the fines imposed. In doing so, the CAT seeks to apply the CJEU preliminary ruling although, as we discuss below, this leads to certain tensions in the approach to market definition and dominance. Before turning to that particular issue, the CAT's key findings are:

- **The generics were potential competitors of GSK in the supply of paroxetine at the time of the relevant agreements.** Applying the test set out by the CJEU, the CAT found the generic companies qualified as potential competitors since (i) they had the intention and inherent ability to enter the UK market, and (ii) there were no 'insurmountable' barriers to such entry. GSK's patents were

not considered an insurmountable barrier to entry since there was a genuine dispute in relation to their validity and whether they were infringed. Similarly, an interim injunction issued against one of the generics could not be considered to be an insurmountable barrier to entry since that company had continued to prepare for trial. The CAT left open the possibility that a different analysis might apply had the patents at issue been molecule patents rather than what it referred to as 'secondary patents'.

- **The settlement agreements had the object of restricting competition.** They did so since they involved net gains to the generics that were (i) not justified by 'proven and legitimate' quid pro quos, and (ii) sufficiently large to act as an incentive to refrain from entry. It was not required that the net gains be larger than the profits the generics would have made if they had successfully entered.

- **The market definition was limited to paroxetine at the relevant time.** Although this confirmed the CMA's view, the analysis is different. The CMA had based its market definition on a quantitative analysis showing that once generic alternatives entered the market, the price of paroxetine fell sharply. As a result, it found that, at all times, the relevant product market was limited to paroxetine. It rejected GSK's argument that the relevant market extended to all SSRI anti-depressants (incidentally, a group including Lundbeck's citalopram, famous for its own 'pay-for-delay' case, which did not, however, include any allegation of abuse of dominance). Instead it held that the qualitative evidence showing no significant therapeutic distinction between paroxetine and other SSRIs was of only theoretical value given the lack of price constraint exercised between the different drugs.

The CAT, by contrast, found that the CMA had been wrong to dismiss this qualitative evidence in the period before the emergence of generic competition. The fact that other SSRIs did not fully constrain paroxetine prices was not decisive, because demand for prescription medicines is not price sensitive. However, the CAT noted the finding of the CJEU that the definition of the relevant market could change once generic companies made preparations to enter. As a result, at the time when the relevant settlement agreements were signed, the relevant market was one for paroxetine alone.

- **GSK was dominant and should have been aware that this was the case.** The CMA had held that GSK should have been aware that it was dominant given the significant reductions in paroxetine prices following generic entry. Again, the CAT held that the CMA's approach was wrong. Significant price reductions on generic entry could not be sufficient evidence of dominance. If they were, then 'almost every patent holder would be dominant'. Instead, the critical question was whether there had been a separate relevant market for paroxetine. The CAT held that the impact of parallel imports of paroxetine into the United Kingdom should have alerted GSK to its potential dominance once preparations for generic entry created a separate market for paroxetine.

- **GSK had abused its dominant position.** GSK had followed a conscious strategy of seeking to prevent generic entry by concluding agreements that induced the generic challenger to delay its effort to enter the market in return for a significant value transfer. It had therefore abused its dominance.

In relation to the penalties imposed, the CAT concluded that the parties ought to have been aware of the anti-competitive nature of the agreements. Nonetheless, it overturned the CMA's decision to impose a fine for abuse of dominance, given the evolving approach to market definition and the overlap with the issues under Chapter I. It also reduced the fines under Chapter I, in particular given the lapse of time between the agreements and the CMA finding of infringement. In total, the CAT reduced the fines on all parties by £27.1 million.

Comment: The Problematic Approach to Market Definition

As set out above, the CAT appears to identify two different periods for market definition. Before the emergence of potential generic competition, the relevant market covered all SSRI anti-depressants. After the emergence of potential generic competition on paroxetine, a relevant market limited to paroxetine emerged.

The CAT indicates that, during the first period, the market must be defined on the basis of qualitative evidence – namely, the evidence (which the CMA had set aside) that there was no significant therapeutic distinction between paroxetine and

other SSRIs. During the second period, however, other SSRIs no longer formed part of the market, and the market was limited to paroxetine alone.

The CAT offers no direct explanation for this change other than to observe that market definitions may vary as market conditions change. That alone cannot be sufficient. The only justification for limiting the market to paroxetine is the evidence that the price of paroxetine fell sharply on generic entry. However, that reflects not simply a change in market definition based on a change in market conditions, but a change in the *basis* on which the market is defined. Specifically, a change from market definition based on qualitative criteria (function) to one based on quantitative criteria (price). This is problematic. A change in the relevant facts may justify a change in the legal outcome, it cannot justify a change in the legal test.

It seems that what lies behind this uncomfortable outcome is the difficult position in which the CAT found itself. On the one hand, the CAT was deeply uncomfortable with the idea of market definition based purely on price effects, particularly in the context of pharmaceutical markets where price sensitivity is rarely a driver of demand for prescription drugs. As the CAT observed, if a large price reduction on generic entry were a sufficient basis for market definition then 'almost every patent holder would be dominant'. On the other hand, adopting a market definition covering all SSRIs would have called into question both the original CMA decision and the preliminary ruling of the CJEU. Reading between the lines, the CAT panel remains attracted to the evidence of Professor Shapiro (much praised in the first judgment, prior to the reference to Luxembourg) which suggested that market definitions could shift depending on the conduct under consideration. As the CAT rightly observes in its May 2021 judgment, the CJEU did not adopt that approach. Nevertheless, that appears still to be a motivating factor for the CAT's ultimate decision. Rather than cast doubt on the overall approach to pay-for-delay settlements, the CAT has chosen to muddy the waters on market definition, reaching a conclusion which is not clearly supported on the facts but – perhaps as an implicit recognition of the problematic nature of this endeavour – cancelling the fine imposed on GSK in respect of the abuse of dominance finding.

It is to be hoped that – for the sake of future legal certainty – the removal of the fine in respect of the abuse aspect of the case does not represent too much of an 'inducement' to GSK not to appeal this aspect of the judgment.