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ORIGINATOR/GENERIC COMPETITION IN THE UK: THE FIRST CMA CASE ON PAY-FOR-DELAY

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An article examining the CMA's Paroxetine decision, the first case in the UK in relation to the application of competition law to patent settlement agreements.

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INTRODUCTION

On 10 August 2016, the Competition and Markets Authority (CMA) published a non-confidential version of its first infringement decision, dated 12 February 2016, in a "pay-for-delay" case and fined three pharmaceutical companies almost £45 million in relation to the supply of paroxetine, an anti-depressant medicine (*Paroxetine - Case CE-9531/11*). The decision relates to agreements and conduct in the years 2001-2004 between the pharmaceutical originator GlaxoSmithKline plc (GSK) and the generic companies Generics (UK) Limited (GUK) and Alpharma Limited (Alpharma).

The decision has been appealed to the Competition Appeal Tribunal (CAT), where hearings started in February 2017 (see *Generic paroxetine delay appeals*).

A second case regarding an allegedly delayed market entry is ongoing and the CMA issued a *statement of objections* against Actavis UK, which is now owned by Intas Pharmaceuticals, and Concordia on 3 March 2017.

FACTUAL BACKGROUND

GSK held a number of patents protecting paroxetine hydrochlorine, in short - paroxetine - the international non-proprietary name of an antidepressant molecule which was marketed in the UK under the brand name Seroxat as tablets and as liquid. The paroxetine hydrochloride molecule patent owned by GSK expired in January 1999 and the data exclusivity expired in December 2000. However, GSK also applied successfully for patents in relation to two separate salt formulations, which expired only in 2006 or later, namely the Hemihydrate Patent and the Anhydrate Patent, and one tableting patent called Dry Tableting Patent.

Between 1997 and 2002, several generic companies, including GUK and Alpharma, were taking steps to enter the UK market. On 18 September 2001, GSK initiated patent infringement proceedings against GUK invoking the Anhydrate Patent and sought successfully an interim injunction to restrain GUK from selling its generic paroxetine in the UK. On 4 December 2001, GSK brought a separate action against GUK for the infringement of the Hemihydrate Patent. On 11 June 2002, GSK initiated an infringement action against Alpharma in relation to the Anhydrate Patent and also applied for an injunction. Before the injunction was granted Alpharma undertook, on 1 August 2002, not to sell or supply any paroxetine product in the UK until the judgment was handed down.

In order to resolve the patent infringement proceedings, the patent disputes with GUK and Alpharma were settled. It is these settlement agreements that became the subject of the CMA's decision

CMA DECISION

The settlement agreements between GSK and the generic companies were brought to the attention of the Office of Fair Trading (OFT), the predecessor of the CMA, by the European Commission (Commission) in 2010. After a preliminary assessment of these agreements, the OFT opened an investigation on 11 August 2011.

On 12 February 2016, the CMA found that the agreements between GSK, GUK and Alpharma constituted infringements of Chapter I and II of the UK Competition Act 1998 and Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).

In setting out the legal test for an agreement which has the object of restricting competition, the CMA relied on the decisional practice of the European Court of Justice (ECJ) and noted that the restriction of competition does not need to be the sole purpose of the agreement. The CMA referred to the ECJ's *Cartes Bancaires* judgment (*Case C-67/13 P - Groupement des Cartes Bancaires v Commission, EU:C:2014:2204*) and stated that in order to determine whether an agreement may be considered to have the object of restricting competition, particular focus must be put on the content of its provisions, its objectives, and its legal and economic context. With regard to restrictive agreements, the CMA also quoted the General Court's *Toshiba* judgment (*Case T-519/09 - Toshiba v Commission, EU:T:2014:263, paragraph 230; affirmed by the ECJ in Case C-373/14 P - Toshiba Corporation v Commission, EU:C:2016:26, paragraphs 30-35*) and highlighted that an agreement which is designed to protect the European producers in their home territories from actual or potential competition, is capable of restricting competition, unless insurmountable barriers to entry to the European market exist that rule out any potential competition.

In this context, the CMA decided that both the GUK agreement and the Alpharma agreement had the object of restricting competition within the meaning of the Chapter I prohibition and Article 101 of the TFEU. The CMA criticised, in particular, that GUK and Alpharma had accepted certain payments and other value transfers from GSK, which it characterised as compensation for their delay to enter the market independently. In particular, the CMA referred, among other things, to marketing allowance payments and a restricted volume of paroxetine, in relation to which GSK sacrificed its profit margin, and instead transferred this margin to Alpharma and to GUK (*Paroxetine, paragraphs 6.91 and 6.155*).

According to the CMA, these cash payments and other value transfers amounted to at least £50.9 million, including at least £17.9 million in transfers to Norton Healthcare Limited (formerly IVAX Pharmaceuticals UK), at least £21.3 million in transfers to GUK, and £11.8 million in transfers to Alpharma (*Paroxetine, paragraph* 8). (The case against IVAX Pharmaceutical UK was closed by the CMA, also on 10 August 2016 *(see case closure summary)*.)

The CMA was of the opinion that such payments and value transfers will be attractive to the generic supplier if the payments from the originator are greater than the returns that the generic supplier could achieve from entering the market independently. On that basis, the CMA concluded that the agreements had the objective aim to restrict competition. The value transfers were conditional on GUK and Alpharma not entering the paroxetine market independently. Moreover, those transfers could not be explained by legitimate commercial objectives.

In addition to having the object of restricting competition, the CMA was of the opinion that the GUK and the Alpharma agreement had the likely effect of restricting competition to an appreciable extent. The CMA stated that the agreements included entry restrictions that prevented GUK and Alpharma from entering the market independently of GSK. Moreover, the CMA concluded that the value transfers from GSK to GUK and Alpharma were made in return for the agreements not to enter the UK paroxetine market. Without sufficient compensation, GUK and Alpharma would not have had an incentive to accept such entry restrictions.

Furthermore, the CMA was of the opinion that GUK and Alpharma assisted GSK in preserving the patent entry barriers by discontinuing their litigation and, thereby, also delayed other companies from entering the paroxetine market. In addition, the CMA highlighted that the transfer of a restricted volume of paroxetine from GSK to GUK and Alpharma, as provided in the settlement agreements, would not increase price competition on GSK. Instead, GUK and Alpharma supported GSK in preserving its market power as no other generic suppliers were as advanced in launching generic paroxetine in the UK.

The CMA also reached the conclusion that the payments by GSK to generic pharmaceutical companies were to induce a delay to their market entry and so constituted an abuse of a dominant position in breach of Article 102 of the TFEU and Chapter II of the Competition Act 1998.

As regards the relevant market, the CMA considered that it is no wider than the supply of paroxetine in the UK. For the assessment whether an undertaking holds a dominant position in the relevant market, the CMA mainly considered whether GSK had substantial market power. The CMA also considered the extent to which GSK faced competitive constraints. By applying these criteria, the CMA came to the conclusion that GSK held a dominant position within the UK paroxetine market at least between January 1998 and November 2003. The CMA found that GSK's market share for the supply of paroxetine to pharmacies and wholesalers was in excess of 60%. Further, GSK remained the sole manufacturer of paroxetine sold in the UK between January 1998 and November 2003 with a market share of 100% at production level.

With respect to GSK's cash payments and other value transfers, the CMA highlighted that such conduct does not constitute "normal competition", but tended to restrict competition. The CMA was of the opinion that the main purpose of these value transfers was to induce the other generic companies to delay their potential independent generic entry.

The CMA imposed a fine on GSK of £37.6 million. In respect of GUK's infringement, the CMA imposed a fine of £5.8 million on Merck KGaA, GUK's former parent and GUK was held jointly and severally liable. As regards Alpharma's infringement, the CMA imposed fines of £1.5 million on Actavis UK Limited (formerly Alpharma Limited), Xellia Pharmaceuticals ApS (formerly Alpharma ApS) and Alpharma LLC (formerly Zoetis Products LLC, Alpharma LLC and Alpharma Inc).

In April 2016, GSK lodged an appeal to the CAT, claiming, among other things, that the agreements with GUK and Alpharma had neither the object nor the effect of restricting competition. GUK and its former parent company Merck KGaA also appealed the CMA decision, as well as Alpharma LLC, Actavis UK Limited and Xellia Pharamceuticals ApS, which are all successors to Alpharma. The hearing of the appeals is listed for 27 February until 30 March 2017.

COMMENT

The CMA decision is the first case in the UK in relation to the application of competition law to patent settlement agreements. It is one of few cases in the aftermath of the Commission's sector inquiry into the pharmaceutical sector in 2008 (*Pharmaceutical Sector Inquiry, Final Report of 8 July 2009*). During that inquiry the Commission reviewed numerous agreements and found only a handful that were problematic. It has since been monitoring patent settlements and so far no other concerns have been made public (*Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016*).

The final report of the sector inquiry pointed out that some patent settlements in the pharmaceutical sector may prove to be problematic from a competition law perspective. The Commission particularly highlighted settlements that may lead to a delay of generic entry in return for a value transfer by the originator company to the generic company and also emphasised the importance of stronger competition law enforcement.

To date the Commission has adopted three decisions since the conclusion of the sector inquiry, in which it has found that certain originators and generic companies had violated Article 101(1) of the TFEU by delaying market entry for their generic pharmaceutical products.

- The first pharma pay-for-delay case adopted at EU level was the *Lundbeck* decision of 19 June 2013, in which the Commission imposed a fine of EUR93.8 million on the Danish pharmaceutical company Lundbeck and fines totalling EUR52,2 million on a number of generic competitors in relation to agreements regarding citalopram, an antidepressant medicine (*Case AT.39226 - Lundbeck*).

  On 8 September 2016, the General Court upheld the Commission's Lundbeck decision and ruled for the first time that pay-for-delay agreements breached Article 101 of the TFEU (*Case T-472/13 - Lundbeck v Commission, EU:T:2016:449*). The judgment of the General Court has been appealed by Lundbeck before the ECJ (*Case C-591/16 P - Lundbeck v Commission (pending)*).
- On 10 December 2013, the Commission fined the US pharmaceutical company Johnson & Johnson and Novartis of Switzerland EUR16 million for delaying market entry of the generic pain-killer fentanyl (*Case AT.39685 - Fentanyl*).
- The third investigation concerned the product perindopril, a cardiovascular medicine (*Case AT.39612 - Perindopril (Servier)*). On 9 July 2014, the Commission imposed fines totalling EUR427.7 million on the French pharmaceutical company Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine and thereby violating Article 101(1) of the TFEU. However, several appeals against the Servier decision are pending before the General Court (*Case T-680/14 - Lupin v Commission (pending)*).

The CMA decision has to be seen in the context of these latest Commission decisions but the facts of all of these cases differ from one another. For example, GSK was awarded with temporary injunctions for patent infringements whereas in *Lundbeck* no patent litigation was pending nor any injunction was obtained (*Lundbeck, paragraph 671*). In *Lundbeck*, the General Court held that the Commission was only required to prove that the generic company had real concrete possibilities of entering the market, at the time the agreements at issue were concluded, and that those possibilities were not purely theoretical but showed a real capacity to enter the market within a sufficiently short period to exert competitive pressure on Lundbeck (*Case AT.39226 - Lundbeck, paragraph 222; see also Batchelor/Sheraton/Carlin/Healy, Lundbeck raises more questions than answers on "Pay-for-Delay" settlements; creates damaging divergence from US law, ECLR 1/2017, at page 4*).

The CMA, on the other hand, did not give any particular weight in its legal assessment to the injunctions granted for the patents in question to GSK, concluding that there was genuine uncertainty as to whether, if litigation had been pursued rather than deferred, GSK would have prevailed (*Paroxetine, paragraph 1.9*).

This approach is unusual also in light of the Commission's findings in the *Servier* decision, which the Commission also based on the fact that many national courts in several EU member states had held that the relevant patents were invalid (*Perindopril (Servier), paragraph 201; see also Schröder, Pay-for-Delay Settlements in the EU: Did the Commission Go Too Far?, ECLR 12/2016, page 509*).

Unlike the Commission's approach in *Lundbeck* and *Fentanyl*, the CMA did not only analyse whether the settlement agreements restricted competition "by object" but also "by effect". This approach might suggest that the CMA itself was not convinced about its own findings of object infringement. Arguing a case in the alternative might make a case stronger on appeal, however, it goes against the object/effect dichotomy in Article 101 of the TFEU. Any object infringement is presumed to have anti-competitive effects whereas not every agreement with anti-competitive effects has the object of restricting competition. The ECJ in its *Cartes Bancaires* case law has certainly clarified the restrictive nature of the category of by object infringements which might have encouraged the CMA to go the extra mile (*Case C-67/13 P - Groupement des Cartes Bancaires v Commission, EU:C:2014:2204, paragraph 58*). However, by doing so the CMA may have weakened its argument that the agreements in the *Paroxetine* case have the object of restricting competition.

As regards the effects analysis, the burden of proof was on the CMA to demonstrate anti-competitive effects of the settlement agreements. The CMA conducted hypothetical counterfactual scenarios and assessed how the paroxetine market would have developed without the agreements in question. In this regard, the CMA stated that competition would have started faster if the generic companies were to have prevailed in the patent court and in the absence of the settlement agreement. The CMA further stated that there was genuine uncertainty as to whether, if litigation had been pursued rather than deferred, GSK would have prevailed.

However, patents are presumed valid unless held invalid by a court. The CMA nevertheless noted that this uncertainty was one of the factors contributing to the generic companies' decisions to invest in the development of generic paroxetine, and that these companies exerted thereby competitive pressure on GSK. Uncertainty is a key feature of competition and legal uncertainty is intrinsic in litigation. The Commission in its *Servier* decision referred to a number of court decision in several EU member states that had held that the relevant patents were invalid. Litigation in the case in front of the CMA had not developed this far and GSK was able to rely on injunctions it had been granted. It is, therefore, questionable how an investment decision of a company combined with legal uncertainty in the normal course of business is a sufficient counterfactual to serve as the basis of a finding of anti-competitive effect.

The CMA, just like the Commission, considered that a high payment from the originator to a generic company is an indicator that the patent(s) in question would be invalid, in particular when the value transfer is higher than the estimated litigation costs. In this regard, the CMA explicitly stated that GSK's value transfer to the generic companies was commercially irrational. The CMA was of the opinion that the purpose of the value transfers was to delay true generic competition, as the payment of value transfers would have made no economic sense if this were not the case. Again, the CMA operates with the factor of uncertainty as there might be many other factors which lead to these value transfers, for example, simply to terminate the legal proceedings and avoid further costs or to avoid disruption to management and business (*see also Schröder, Pay-for-Delay Settlements in the EU: Did the Commission Go Too Far?, ECLR 12/2016, page 507*).

The *Paroxetine* appeal will be closely watched and it remains to be seen whether the CMA's analysis of the facts will withstand the test established in *Cartes Bancaire* and whether the settlement agreements were a response to general uncertainty or had the additional element of paying off a competitor. The CAT judgment is expected in early summer 2017. It would be a questionable outcome if, from a practical point of view, patent settlement agreements were to become less attractive for companies who might be discouraged by the CMA and Commission decisions, a development already noticeable as a result of the Commission decisions in *Lundbeck* and *Fentanyl*. Since 2013 the number of settlements in patent proceedings has gone down (*Commission, 7th Report on the Monitoring of Patent Settlements, 13 December 2016, paragraph 2*). While this might be the result of reduced patent litigation, discouraging companies to settle patent litigation would have significant negative effects on the parties and ultimately on innovation and the consumer.