GSK AND OTHERS FINED AS CMA CONCLUDES INVESTIGATION INTO PAROXETINE PAY-FOR-DELAY SETTLEMENTS

DERVLA BRODERICK
Olswang LLP

Introduction

On 12 February 2016 the UK Competition and Markets Authority ('the CMA') announced the conclusion of its lengthy investigation into so-called 'pay-for-delay' settlements relating to GlaxoSmithKline's ('GSK') blockbuster anti-depressant, paroxetine. The CMA has imposed record fines totalling £45 million on three companies which were found to have infringed European Union ('EU') and UK competition law by entering into agreements to delay the market entry of generic versions of the drug in the United Kingdom. GSK has shouldered the bulk of the fines, with the remainder going to generic producers, Generics (UK) Limited ('GUK') and Alpharma Limited ('Alpharma'). A fourth company, Norton Healthcare Limited (formerly IVAX Pharmaceuticals UK), was also party to the CMA's investigation but was not found liable.

This article looks at the background to the case and the legal basis for the infringement findings, providing some insight into the wider EU law context of the CMA's decision.

Details of the Settlements

The CMA's decision centres on steps taken by GSK to protect the position of its branded version of paroxetine, Seroxat, in advance of the expiry of certain process patents. At the time Seroxat was expected to eclipse Prozac as the world's most prescribed anti-depressant and was one of GSK's best-selling products.

Lucrative products are prime targets for generic competition and in 2001, GUK and Alpharma (among others) were taking steps to launch generic versions of paroxetine in the United Kingdom. GSK commenced patent infringement proceedings and was granted interim injunctions restraining the two generic manufacturers from entering the UK market pending a full hearing. Indeed, the decision which granted GSK an interim injunction against GUK was considered a highly significant decision for generic manufacturers at the time. In reaching his decision to grant the interim injunction, Jacob J took into account the fact that GUK had known about the patent for a long time and therefore could have taken steps (by, for example, applying for a declaration of non-infringement, launching a petition to revoke or inviting the claimant to sue) to clear its position prior to the intended launch of its product. It was felt by many commentators that this decision placed a high burden on a generic company planning to launch a product where that company was aware of a competitor's patent and the possibility of infringement.

However, the parties reached settlement and neither case proceeded to trial. GUK and Alpharma's settlements with GSK were on terms which precluded their independent entry into the UK paroxetine market. As consideration, GUK and Alpharma received cash payments and were appointed as distributors for a limited volume of supply of GSK product, effectively transferring profit from GSK to the generics without opening the market for paroxetine to price competition. The agreements were in place from 13 March 2002 to 1 July 2004 in the case of the GUK agreement and from 12 November 2002 to 13 February 2004 in the case of the Alpharma agreement.

The CMA's Infringement Findings

The CMA has found the settlements concluded between GSK and the two generic manufacturers infringed the prohibition on anticompetitive agreements in Chapter I of the UK

Competition Act 1998 ('CA98') and/or Article 101 of the Treaty on the Functioning of the EU. It has also found that GSK infringed the prohibition on abuse of a dominant position in Chapter II CA98 by making cash payments and other value transfers to induce potential competitors to delay their potential independent entry to the UK paroxetine market.

The CMA concluded that the infringements under Chapter I/ Article 101(1) lasted for the duration of the agreements while the Chapter II infringements lasted from 3 October 2001 until 30 November 2003. The arrangements are said to have deferred the competition that the threat of independent generic entry could offer, and potentially deprived the UK National Health Service ('NHS') of the significant price falls that generally result from generic competition.

It is worth noting that the fines in this case are attributed to a former parent company as well as to successor companies. The total penalty in respect of GUK's infringement is £5,841,286. Merck KGaA, GUK's former parent, is liable for the total amount and of that amount GUK is jointly and severally liable, with Merck KGaA, for £2,732,765. The total penalty in respect of Alpharma's infringement is £1,542,860, for which each of its successor companies (Actavis UK Limited, Xellia Pharmaceuticals ApS and Alpharma LLC) are jointly and severally liable.

Timeline of the CMA's Investigation

The European Commission ('the Commission') brought the paroxetine agreements to the attention of the Office of Fair Trading ('the OFT', the CMA's predecessor) in 2010. How the Commission came to be aware of the agreements is not clear as yet (the CMA's decision has not yet been published). One possibility is that the Commission was first alerted to the arrangements by way of its annual patent settlement monitoring process (see further below). Alternatively, it may have gained knowledge through a separate investigation into GSK's conduct regarding Seroxat which commenced in 2005. That investigation was initiated following a complaint that GSK abused its dominant position in the market for Seroxat through conduct which included the enforcement of its IP rights, litigation surrounding regulatory approvals and marketing of the drug in Europe. The Commission carried out inspections of GSK premises but the investigation closed in 2012 when the complainant, believed to be a generic company, Synthon, withdrew its complaint.

In August 2011, the OFT opened its investigation into possible anticompetitive agreements for the supply of paroxetine in the United Kingdom. This was followed by an announcement on 19 April 2013 that it had sent a statement of objections to GSK and Alpharma, GUK and Norton Healthcare. The CMA sent a supplementary statement of objections to all parties in October 2014. The CMA delayed issuing its final decision by around six months citing the need for additional time to consider the parties' responses.

GSK Likely to Face Damages Claims

According to the CMA's announcement, in this case, when independent generic entry eventually took place at the end of 2003, average paroxetine prices dropped by over 70 per cent in two years. The UK public health services are likely to seek to recoup the amount they were overcharged in this period, when price competition was illegally restricted by the anticompetitive conduct. The NHS in Wales has already indicated that it will pursue such a damages claim.

Indeed, given the current pressure on health authority funding, one could say that the NHS is under an obligation to seek damages in these cases where there is an opportunity to bolster the public purse. Several UK health authorities brought damages claims against Reckitt Benckiser following the OFT's decision regarding anticompetitive conduct in relation to heartburn treatment, Gaviscon. The OFT's decision found that Reckitt Benckiser had abused a dominant position by manipulating the NHS prescription process for its product. The NHS actions were settled in 2014 although actions brought by generic manufacturers continued. There are also several ongoing claims against Servier, which was the subject of a Commission infringement decision in 2014 (see further below).

GSK may also face actions from other generic manufacturers who incurred loss as a result of GSK's anticompetitive conduct. For example, around the same time as GSK reached settlement agreements with Alpharma and GUK, it was involved in ongoing patent litigation with generic companies, Apotex Europe Limited ('Apotex'), Neolab Limited ('Neolab')

and Waymade Healthcase Plc ('Waymade'). In October 2002, Neolab, Apotex and Waymade informed GSK of their intention to launch generic paroxetine in the United Kingdom and began patent revocation proceedings in respect of GSK's patent. In response, GSK began its own proceedings alleging infringement of its patented processes and was granted interim injunctions restraining the companies from launching their product. The trial resulted in the patent being revoked in December 2003 and GSK advised that it would not seek to maintain the interim injunction in force during the pendency of its appeal against that ruling. Consequently, generic paroxetine was launched in the United Kingdom, resulting in the dramatic fall in price referred to above.

Once the CMA's decision is published, it will be most interesting to see what part these proceedings played in the CMA's assessment of GSK's infringements, in particular as regards its abuse of dominance, and whether the CMA will provide any helpful commentary on the harm suffered by potential generic competitors of GSK.

European Context

The full decision should also provide insight into whether the CMA has deviated in any way from the legal assessment used by the Commission in its recent decisions on pay-for-delay agreements. As discussed below, these cases are currently under appeal and the court's judgment may well have implications for the wider application of EU competition law in pay-for-delay challenges, as well as for future appeals and damages actions in the CMA's *Paroxetine* case.

The *Paroxetine* case is the CMA's first decision on pay-for-delay settlements although there is precedent at an EU level originating from the Commission's inquiry into competition in the EU pharmaceutical sector which commenced in 2008. The Commission's final report on the sector inquiry found, *inter alia*, that settlements of patent-related disputes between originator and generic companies could be contrary to competition law in certain circumstances. It identified a particular concern to be those settlements under which generic market entry is restricted or delayed in exchange for benefits transferred from the originator to the generic company (that is, 'pay-for-delay' deals).

Following the sector inquiry, the Commission has adopted two decisions against pharmaceutical companies involved in pay-for-delay agreements. The first decision, in 2013, concerned another lucrative anti-depressant, Citalopram, which Denmark-based Lundbeck developed in the late 1980s ('the *Citalopram* decision'). By 2002, Lundbeck's patent protection for Citalopram had all but expired and a number of generic companies were getting ready to enter several different European national markets. However, the Commission found that in order to protect its monopoly profits from Citalopram, Lundbeck agreed with several potential market entrants that they would not launch the product in competition with Lundbeck in exchange for payment. These agreements were not settlements of litigation as such, but rather agreements concluded in the context of a patent dispute. According to a speech by Joaquín Almunia, former Commission Vice-President, the documents seized by the Commission include reference to the companies involved as a '*club*' who shared a '*pile of dollars*'.

This was followed in 2014 by findings of infringement, and fines in excess of €400 million, against Servier and generic producers of high blood pressure medicine perindopril ('the *Servier* decision'). Like the CMA's *Paroxetine* decision, the Commission found that Servier abused its dominant market position in respect of perindopril, in order to protect what Servier termed its '*dairy cow*' when the patent for the drug's molecule expired in 2003. Servier's strategy included acquiring the principal source of generic production and entering into several pay-for-delay agreements with potential generic competitors.

The Commission found that in both cases the agreements and conduct caused consumer harm by delaying generic entry and maintaining unnecessarily high prices. However, as with many cases at the edge of the IP and competition law interface, the legal basis of the Commission's decisions is not entirely uncontroversial. With judgment expected in the *Citalopram* appeal later this year, it is hoped that the court will provide certainty on a number of aspects of how the EU competition rules on anticompetitive agreements should apply to patent settlement agreements.

Patent Settlements: A Conflict Between IP and Competition Law

The Commission's *Citalopram* decision in particular raises a number of issues which IP and competition lawyers alike find unsettling. Here we look briefly at two such issues. The first centres on the circumstances in which a settlement of patent litigation involving a payment from originator to generic can ever avoid infringement of competition law in circumstances where the Lundbeck agreements were characterised as 'by object' infringements (that is, an infringement so obviously harmful to competition that the regulator did not have to look at the agreements' effects). The second is to do with the position of generic manufacturers as potential competitors and the requirement that their market entry needs to be a real and concrete possibility in order for an agreement to have the object or effect of restricting competition.

As regards the first concern, the Commission recognises that not all patent settlements will infringe competition law, even if the settlement limits the commercial autonomy of at least one of the parties. However, in the *Citalopram* decision, the Commission notes that '*while a patent holder has the right to oppose possible infringement of its patent, patent law does not provide for a right to pay actual or potential competitors to stay out of the market or to refrain from challenging a patent prior to entering the market*.'

Settlements involving payments or value transfers are examined as part of the Commission's patent settlement monitoring exercise. The Commission started monitoring patent settlements between originator and generic companies following the publication of its report into the EU pharmaceutical sector in 2009. The Commission's stated aims as regards the monitoring exercise are '*to better understand the use and type of agreement and to identify those agreements that delay generic entry to the detriment of the European consumer possibly in violation of EU competition law*'. In the latest report, published in December 2015, the Commission again analyses settlement agreements by reference to one of three categories. Categories A (covering settlements involving no restriction on generic entry) and B.I (covering settlements limiting generic entry with no 'value transfer' from the originator to the generic company) are generally deemed unproblematic. Category B.II agreements, which include a limitation on generic entry and involve a 'value transfer', are said by the Commission to attract the highest degree of antitrust scrutiny.

The *Citalopram* decision provides some further colour on this, stating that any agreement which induces the generic company to exit the market or not to enter the market for a certain period of time will almost always raise competition concerns. The decision pays little attention to the potential for infringement of the patent by the generic and how this plays into both parties' assessment of the benefits of a settlement. However, the Commission does note that the level of payment to the generic may provide some indication of how the originator estimates the chance of its patent being found invalid. Parties are generally advised to proceed with caution when seeking to settle a patent dispute on terms involving 'exclusionary' payments.

As regards the categorisation of generic manufacturers as potential competitors when it comes to market entry, it may feel to some that like the Commission's analysis in the *Citalopram* decision it may have been overly simplistic in this regard. For a generic to enter into competition with a branded product, it needs access to non-infringing product as well as the appropriate marketing authorisations. In its appeal against the *Citalopram* decision, one of the generic manufacturers, Arrow Generics Limited ('Arrow'), has argued that in fact it had no reliable product to bring to market at the time at which the Lundbeck agreement was on the table. Additional arguments also point to the significant risks involved in patent litigation and deny that the existence of potential competition can result from the possibility that the originator's patents would be found to be infringing.

Indeed, bringing it back to the interim injunction granted to GSK in respect of GUK's potential launch of paroxetine mentioned at the outset, Arrow also argues that the high burden that decision placed on generic manufacturers at that time must be taken into account in assessing whether Arrow was in fact a potential competitor to Lundbeck at the time it agreed not to launch generic citalopram. Of course, any weight placed on this by the General Court may also prove useful to the parties in a future appeal of the CMA's *Paroxetine* decision.

Conclusion

Given the complexities of the legal issues raised by pay-for-delay agreements under competition law, the publication of the CMA's decision will be widely anticipated. It will be particularly interesting to see whether the CMA has taken guidance from the experience of the Commission and placed more emphasis on the risks associated with the underlying patent litigation on parties' willingness to enter into an agreement (it is already noteworthy that the CMA relies on the Chapter II CA98 prohibition against GSK in addition to the prohibition on anticompetitive agreements). It also remains to be seen what impact the General Court's judgment in the *Citalopram* case might have on both appeals of the *Paroxetine* decision and the potential for damages claims.