SLAUGHTER AND MAY

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EU judges prescribe smaller fine for Servier following "pay-for-delay" appeal

On 12 December 2018 the European General Court (GC) **partially overturned** a 2014 **European Commission decision** fining Servier and six generic pharmaceutical firms for abuse of dominance and/or involvement in illegal "pay-for-delay" agreements. The GC found that one of the agreements in question was not anti-competitive, and that the Commission had incorrectly defined the relevant product market in finding that Servier had abused a dominant position. As a result, the GC reduced Servier's fine by over €100 million, to €228 million. The GC nevertheless confirmed that the remaining "pay-for-delay" agreements agreed by Servier were restrictions of competition by object.

Background

The Servier group developed perindopril, a prescription medicine used to treat heart failure and high blood pressure. Whilst the perindopril compound patent expired over the course of the 2000s, in 2004 Servier acquired a new patent relating to the active pharmaceutical ingredient of perindopril and its manufacturing processes (the 947 patent). In light of challenges to that patent, Servier entered into settlement agreements with a number of generic companies, namely Niche, Unichem, Matrix, Teva, Krka and Lupin. Under these settlement agreements, the generic companies were obliged to refrain from entering the market or challenging the 947 patent.

In July 2014 the Commission found that these patent settlements amounted to illegal "pay-for-delay" agreements, which constituted restrictions of competition by object and effect. In addition, the Commission found Servier guilty of abusing a dominant position in the markets for perindopril in France, the Netherlands, Poland and the UK. The Commission imposed fines on the companies totalling €428 million.

The GC's decision

Patent settlement agreements

The GC held that all but one of the settlement agreements constituted restrictions of competition by object. In reaching this finding, the GC concluded

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that the generic companies in question were potential competitors of Servier given the real possibility of them entering the market. The GC reached this conclusion despite the barriers arising from Servier's patents, the difficulties in obtaining marketing authorisations, technical problems in developing the product in question and the costs involved.

The GC recognised the importance of settlement agreements in avoiding litigation – as a result, the adoption of patent settlement agreements does not necessarily amount to an infringement of competition law.

Nevertheless, the GC agreed with the Commission's reasoning that the grant by a patent owner of advantages intended to induce a generic company not to enter the market or challenge the patent, must be considered a market exclusion agreement (even if contained in a settlement agreement). The agreements concluded between Servier and Niche, Unichem, Matrix, Teva and Lupin therefore amounted to market exclusion agreements restrictive of competition by object.

Regarding the agreement with Krka, the GC held that there was no evidence of an inducement by Servier in return for Krka withdrawing from the market (and therefore no restriction of competition by object). In this regard, the GC did not agree with the Commission's finding that the 3 per cent royalty payable by Krka to Servier under a licence agreement relating to the 947 patent was not at arm's length. The GC also did not consider that the agreement amounted to a restriction of competition by effect, since there was no evidence that Krka would probably have entered the market absent the settlement agreement, or that its continuation of proceedings against the 947 patent would have accelerated invalidation of the patent. The GC therefore annulled the fines imposed on Servier and Krka for the agreement.

Abuse of dominance

In relation to the alleged abuse of dominance by Servier, the GC ruled that the Commission had incorrectly defined the relevant product market in its analysis. Rather than construing the relevant product market for perindopril as one which encompassed other drugs in the ACE inhibitor class, the Commission had defined the market by reference to a single molecule within this class (namely, perindopril, in its originator and generic versions).

The GC noted that, unlike in other sectors, demand for prescription medicines is determined by the prescribing doctor rather than the end consumer. Since doctors are less concerned with price and more focused on therapeutic use, non-price competitive pressures are also relevant in determining the scope of the relevant product market. The GC indicated that the Commission had misunderstood this dynamic, and consequently, the breadth of the product market. The Commission had therefore been wrong to find that Servier held a dominant position and had abused that position. The GC annulled the fine imposed on Servier for abuse of a dominant position.

Conclusion

On the one hand, the GC's finding that five of the settlement agreements constituted restrictions of competition by object provides further support for the Commission's approach to "pay-for-delay" agreements (consistent with the GC's decision in *Lundbeck*[1]), which similarly characterised certain patent

[1] Case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd v European Commission*, judgment of 8 September 2016.

settlement agreements as restrictions of competition by object. Whether or not the European Court of Justice will agree in the context of Lundbeck's appeal remains to be seen.

On the other hand, the GC's finding that the Commission erred in defining the relevant product market in the case provides a reminder that the Commission's pursuit of such agreements will not go unchecked. Such findings are uncommon, given the determination of market definition is highly fact sensitive and forms a fundamental part of the Commission's analysis. Accordingly, the GC's ruling might have some containing effect on dominance cases in the pharmaceutical sector, at least in the near future, the drug manufacturers having received much attention from the Commission in recent years.

Other developments

Antitrust

CMA publishes Final Report in Investment Consultants Market Investigation

On 12 December 2018 the Competition and Markets Authority (CMA) **published** its Final Report concluding its market investigation into the investment consultancy and fiduciary management sector.[2] The CMA concluded that these markets are not highly concentrated, that barriers to entry and expansion are not high, and that both markets are growing. Nevertheless, the CMA identified two features of these markets which it considers give rise to an adverse effect on competition.

First, there is a low level of engagement by some pension trustees in choosing and monitoring their investment consultant, and it is difficult for pension trustees to access the information needed to evaluate the quality and value of the services they receive. Second, firms which provide both investment consultancy and fiduciary management have an incumbency advantage as a result of investment consultants steering customers towards their own fiduciary management services. This problem is exacerbated by relatively high switching costs and the difficulty of accessing information on fiduciary mangers' fees and historic performance.

The Final Report sets out remedies for these adverse effects on competition, which include the following requirements: (i) pension trustees must tender when they first purchase fiduciary management services (above a minimum threshold) and run a competitive tender within five years if they have already awarded a fiduciary management mandate without doing so; (ii) investment consultants must separate marketing of their fiduciary management service from their investment advice service and inform customers of their duty to tender in most cases before buying fiduciary management services; (iii) fiduciary management firms must provide better and comparable information on fees and performance for prospective customers and on fees for existing customers; (iv) pension trustees must set objectives for their investment consultant, to assess the quality of investment advice they receive; and (v) investment consultancy and fiduciary management providers must report performance of any recommended asset management products or funds using basic minimum standards.

The CMA carried out its investigation after a reference from the Financial Conduct Authority (FCA). As part of the next steps, it expects both the FCA and The Pensions Regulator to take on new regulatory duties to oversee the sector. The CMA's remedies will be implemented by way of CMA order, which will be

[2] Investment consultants advise pension trustees, who oversee companies' pension schemes, on how to invest their funds. Some pension trustees delegate investment decisions to fiduciary managers. A number of firms offer both services.

subject to a formal consultation in early 2019. The CMA expects most of its remedies to be in place by the end of 2019.

ECN+ Directive: Council adopts law boosting EU antitrust regulators' powers

On 4 December 2018 the Council of the EU **adopted** a Directive (the so-called "ECN+ Directive") originally **proposed** by the European Commission in March 2017 to complement Council Regulation (EC) 1/2003, which, since 2004, has enabled national competition authorities (NCAs) to play a significant role as enforcers of EU antitrust rules in cooperation with the Commission through the European Competition Network (ECN).

The adoption follows an **agreement** reached by the Council and the European Parliament in May 2018, which confirmed the Commission's view that NCAs need more effective enforcement tools. Regulation 1/2003 does not address the means and instruments by which NCAs apply EU antitrust rules, leading to divergences in application of these rules.

The ECN+ Directive is therefore designed to bring about a "*genuine common competition enforcement area*" by establishing a set of minimum guarantees, including:

- *Independence and resources*: Ensuring that NCAs have the necessary human, financial and technical resources and that they perform their duties and exercise their powers independently, without interferences that would put at risk their impartiality;
- *Powers*: Providing a set of core investigatory powers, which, among other things, enable NCAs to enter both public and private premises (including private homes) and to inspect records irrespective of their medium (e.g. mobiles phones, laptops, cloud storage, etc.);
- *Sanctions*: Ensuring that NCAs can impose effective, proportionate and dissuasive fines for breach of EU antitrust rules, with a maximum fine of not less than 10 per cent of the total worldwide turnover (including rules for parental and successor liability preventing undertakings from avoiding fines through restructuring);
- *Leniency*: Setting coordinated leniency rules that enable NCAs to grant immunity from, or a reduction in, fines, thus increasing legal certainty for infringing companies whilst maintaining their incentives to cooperate with authorities;[3] and
- *Mutual assistance*: Ensuring that NCAs assist each other effectively when requested to carry out an inspection, or any other fact-finding measure, in their own territory on behalf of another NCA.

Member States will now have two years to transpose the provisions of the ECN+ Directive into national law.

SAMR fines three glacial acetic acid suppliers RMB 6.25m for price collusion and confiscates illegal gains of RMB 6.58m

On 6 December 2018 China's State Administration for Market Regulation (SAMR) **announced** that it had fined three suppliers of the active pharmaceutical ingredient (API) glacial acetic acid, namely Chengdu Huayi Pharmaceutical Excipients Manufacturing, Sichuan Jinshan Pharmaceutical, and Taishan Xinning Pharmaceutical (the Suppliers), a total of RMB 6.25 million (equivalent to 4 per cent of each supplier's

[3] Where an applicant has applied to the Commission for leniency in relation to an alleged cartel affecting at least three Member States, it should be able to submit summarised versions of that application to NCAs.

sales in 2017) for price fixing. SAMR also separately confiscated RMB 6.58m of illegal gains from such activities. As an input for the manufacturing of pharmaceuticals, glacial acetic acid is mainly used in the production of haemodialysis concentrates for the treatment of diseases such as advanced kidney failure and uraemia.

SAMR received a complaint in July 2018, which alleged that some glacial acetic acid suppliers had jointly raised prices. SAMR's investigation revealed that, between October 2017 and February 2018, there were extensive exchanges of information on market conditions and sales, as well as discussions on raising prices, amongst the Suppliers. The Suppliers subsequently agreed to raise jointly the price of glacial acetic acid on 1 March 2018 by 211 per cent to 371 per cent.

In addition to imposing a total penalty of RMB 12.83 million against the Suppliers, SAMR condemned the anti-competitive conduct of the Suppliers as severe in nature and causing serious damage, for three reasons:

- first, competition was damaged significantly, as the Suppliers are the only three glacial acetic acid manufacturers in the market;
- second, the cost of manufacturing for downstream pharmaceutical companies was increased drastically; and
- third, such increase in cost caused downstream pharmaceutical companies to reduce or cease production of haemodialysis concentrates, which in turn jeopardised the treatment of patients requiring haemodialysis.

In its announcement, SAMR pledged to continue to strengthen competition enforcement in the API sector in China so as to protect patients and the relevant market operators. This stance is in line with the SAMR's **campaign** earlier this year to crack down on unfair competition in particular sectors, including the pharmaceutical sector and **API sector**.

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