SLAUGHTER AND MAY

Competition & Regulatory Newsletter

18 - 31 October 2017 / Issue 22

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CMA opens four new pharma antitrust probes

On 13 and 18 October 2017 the Competition and Markets Authority (CMA) announced that it had launched four separate antitrust investigations into alleged anti-competitive practices regarding generic products in the pharmaceutical industry.

The four investigations cover alleged anti-competitive agreements, concerted practices and, in some cases, abuse of dominance. The **first** investigation has been launched under the Chapter I prohibition in the Competition Act 1998 (CA 1998) and Article 101 of the Treaty on the Functioning of the European Union (TFEU). It relates to suspected anti-competitive agreements and concerted practices in relation to generic pharmaceutical products. In the **second**, **third** and **fourth** cases, the CMA is examining these types of potential breaches alongside alleged abuse of dominance under the Chapter II prohibition in the CA 1998 and Article 102 of the TFEU.

The parties under investigation

At this stage, two pharma companies have confirmed that they are amongst the parties being investigated in these new probes. Concordia International Corp., a Canadian-based specialty pharma company **said** on 11 October 2017 that "certain of its products" formed part of the CMA's inquiry. Concordia, which focuses on off-patent drugs, added that it would "work constructively" with the CMA to resolve matters, noting that the investigation included matters that pre-date its ownership of the business. Concordia is already the subject of two CMA investigations relating to excessive pricing and 'pay-for-delay' agreements.

Similarly, the South African pharma company Aspen Pharmacare **confirmed** on 13 October 2017 that it was under investigation by the CMA. Aspen said that the investigation related to alleged anti-competitive conduct in the supply of two drugs, Fludrocortisone Acetate and Dexamethasone, in the UK. Aspen described the investigation as being "at an early, information-gathering stage" and said that it was not currently able to comment further. Aspen is also being investigated by the European Commission for alleged excessive pricing, after it was **fined** by the Italian competition authority for excessive pricing in October 2016.

For further information on any competition related matter, please contact the **Competition Group** or your usual Slaughter and May contact.

Wider context

The CMA and the Commission have carried out various investigations into generic drugs markets over recent years, focussing on 'pay-for-delay' agreements to prevent the entry of generic drugs into the market and excessive pricing. The CMA has also investigated a potentially unlawful discount scheme allegedly designed to impede competition from 'biosimilars'.

'Pay-for-delay' cases

The Commission **informed** Teva (Actavis' parent company) in July 2017 of its preliminary view that an agreement between Teva and Cephalon, another drug manufacturer, breached EU antitrust rules. It was alleged that under the agreement, Cephalon paid Teva not to sell a generic alternative to Cephalon's sleep disorder drug, modafnil, in the EEA. This follows on from a $1.2 billion **settlement** between Teva and the US Federal Trade Commission in May 2015 in relation to a series of 'pay-for-delay' agreements.

In March 2017 the CMA **alleged** that Concordia and Actavis UK Ltd (now known as Accord Healthcare) had entered into an anti-competitive agreement. The CMA claims that Actavis, the sole supplier of generic hydrocortisone tablets in the UK between 2008 and 2015, incentivised Concordia not to enter the UK market with its own version of the generic drug by providing it with a fixed supply of the tablets at a very low price to resell in the UK. The CMA issued a Statement of Objections which provisionally found that both parties entered into anti-competitive agreements, and that Actavis abused its dominant position by inducing Concordia to delay its entry into the UK market.

Excessive pricing cases

In December 2016 the CMA **imposed** an £84.2 million fine on Pfizer and a £5.2 million fine on its distributor Flynn Pharma after finding that both companies had abused their dominance by charging excessive prices in the UK for phenytoin sodium capsules, an anti-epilepsy drug. Pfizer had sold the rights to distribute the drug to Flynn, which subsequently made the drug an unbranded generic, meaning that it was no longer subject to price controls. The price that the NHS was charged for 100mg packs of the drug rose from £2.83 to £67.50, meaning that overall NHS expenditure increased from around £2 million in 2012 to approximately £50 million in 2013. The CMA found that the parties had abused a dominant position in the market for the manufacture and supply of phenytoin sodium capsules by charging excessive and unfair prices. The decision is currently under appeal at the Competition Appeal Tribunal.

The CMA **launched** investigation into Concordia in October 2016, relating to allegations of excessive pricing in the supply of certain pharmaceutical products, including to the NHS. Concordia **confirmed** that the investigation related to "generic and legacy" pharmaceutical products which it has acquired as a result of its purchase of Amdipharm. The CMA expects to decide whether it will proceed with the investigation later this month.

Additionally, the CMA **accused** Actavis of excessive pricing of hydrocortisone tablets in a Statement of Objections issued in December 2016, noting that the amount the NHS was charged for 10mg packs of the drug rose from £0.70 in April 2008, when the drug was branded, to £88.00 for the unbranded generic drug by March 2016. The CMA is currently considering the written and oral representations that the parties have made in response to its Statement of Objections.

The Commission **announced** in May 2017 that it had opened an Article 102 investigation into concerns that Aspen had abused a dominant market position by engaging in excessive pricing concerning five cancer drugs. The Commission plans to investigate information suggesting that Aspen has imposed price increases of several hundred per cent. The ongoing investigation covers all of the EEA apart from Italy, where the national competition authority has already completed its own investigation into Aspen, resulting in a €5 million fine for excessive pricing.

Unlawful discount case

In May 2017 the CMA issued a Statement of Objections which provisionally **found** that Merck Sharp & Dohme (MSD), a subsidiary of US pharma giant Merck, had operated an anti-competitive discount scheme for its branded drug Remicade. Remicade is MSD's brand name for the drug infliximab, which treats autoimmune conditions such as Crohn's disease and rheumatoid arthritis. The CMA alleged that the discount scheme was structured to restrict competition from 'biosimilar' versions of infliximab, similar but not identical drugs produced using cheaper methods. It is currently receiving written and oral representations in response to its Statement of Objections.

Investigation process

The CMA has published case timetables for each of the four new investigations. These indicate that the CMA will conduct an initial investigation, involving information gathering, analysis and review between now and April 2018.

Once the investigations have been completed, there is a range of potential outcomes. These include the CMA finding that there are no grounds for further action, agreeing to bring the investigation to a close in return for commitments from a business regarding its future conduct, or issuing a Statement of Objections setting out a provisional view that the conduct under investigation amounts to an infringement. If the CMA does issue a Statement of Objections, the parties will be able to make representations prior to a final infringement decision. The infringement decision will include details of any financial penalty imposed on the relevant parties.

Excessive pricing of generic drugs is highly controversial, and has received scrutiny from antitrust authorities and government in the UK, Europe and the US, especially where price rises have increased costs for public health authorities. In the UK, the Health Service Medical Supplies (Costs) Act 2017 **received** Royal Assent in April 2017, which gives the Secretary of State for Health broad powers to limit the price of unbranded generic drugs, which were previously not subject to price regulation.

These new investigations again demonstrate that the CMA is unafraid to take a robust approach to investigating anti-competitive conduct relating to generic drugs.

Other developments

Antitrust

European Commission raids German car manufacturers

European Commission officials have conducted a series of unannounced inspections of the premises of several German car manufacturers. The Commission undertook the inspections due to its concerns that several car manufacturing companies in Germany may have breached EU antitrust law under Article 101 of the TFEU, which prohibits cartels and restrictive business practices.

On 20 October 2017 the Commission announced that its officials had carried out dawn raids on 16 October 2017 at the premises of a car manufacturer in Germany. The officials were accompanied by officials from the German national competition authority. On the same day Daimler AG board member Bodo Uebber confirmed in a press briefing that the company had filed a leniency application with the Commission in connection with the possible carmaker cartel. The Commission made a further announcement on 23 October 2017 that its officials had that day carried out inspections at the premises of other German car manufacturers. The Commission officials were again accompanied by counterparts from the German national competition authority.

Inspections are the first step in investigations of suspected anti-competitive behaviour, but do not mean that the companies involved are necessarily guilty of anti-competitive practices. There is no legal time limit by which the Commission has to complete inquiries into anti-competitive conduct. The length of the inquiry will depend on a range of factors, including the complexity of the case and the extent to which the companies involved cooperate with the Commission.

As part of its efforts to refine its tools for detecting cartels, the Commission in March 2017 launched a whistleblower tool which allows two-way communication with informants who wish to remain anonymous. As indicated in a recent speech by Competition Director-General Laitenberger, the innovation was well received: the relevant Commission website page that includes the tool received around 9,000 visits last month.

General Court rules that watchmakers may restrict supply of parts to authorised repairers only

On 23 October 2017 the General Court (GC) handed down a judgment dismissing an appeal by the Confédération européenne des associations d'horlogers-réparateurs (European confederation of watch repairers' associations (CEAHR)) against the European Commission's July 2014 decision to reject CEAHR's complaint over the refusal of several prestige/luxury watch manufacturers[1] to supply spare parts to independent watch repairers. The Commission concluded that there was a limited prospect of finding that the manufacturers' refusal to make spare parts available beyond their networks of authorised repairers

[1] The Swatch Group, Richemont, LVMH Moët Hennessy-Louis Vuitton, Rolex, Audemars Piguet and Patek Philippe.

would breach Article 101 or 102 of the TFEU. This represents the second time CEAHR's complaint has been rejected.[2]

The GC confirmed that a selective distribution system (and, by analogy, a selective repair system) can conform with EU antitrust rules so long as it is objectively justified, non-discriminatory and proportionate, and that these conditions may be fulfilled in relation to the Swiss watchmakers' repair networks. It agreed with the Commission's finding that the watchmakers had legitimate justifications for refusing to supply non-accredited repairers, such as the prevention of counterfeiting and the preservation of brand image and high-quality and technologically advanced products. The authorised repairers were selected on the basis of qualitative criteria and the selective systems were open to all independent repairers that satisfied those criteria. The GC also rejected CEAHR's argument that a selective distribution system is only permitted if it does not eliminate all competition; it is sufficient that it meets the criteria mentioned above.

The ruling also confirmed that refusal to supply by a dominant company constitutes an abuse within the meaning of Article 102 of the TFEU only in certain circumstances, i.e. where there is a risk of all effective competition being eliminated. In the present case, the luxury watch manufacturers' refusal to supply independent repairers is unlikely to be sufficient to establish abusive conduct. The GC also dismissed CEAHR's argument that the refusal to supply resulted from an agreement or concerted practice, as the watchmakers had adopted a series of independent commercial decisions over a relatively long period of time.

Hong Kong Competition Tribunal issues judgment on the right against self-incrimination

In October 2017 the Hong Kong Competition Tribunal (Tribunal) handed down its **judgment** on applications made by two respondents, Nutanix and BT, to strike out certain statements given by their employees during interviews conducted by the Hong Kong Competition Commission (HKCC) and to debar the HKCC from using such statements in the upcoming substantive hearing. The present case concerned an application by the HKCC earlier this year against five IT companies for allegedly engaging in bid-rigging activities. This also marked the first case that the HKCC brought before the Tribunal since the Competition Ordinance (CO) commenced full operation in December 2015.

Under section 42 of the CO, the HKCC has the power to issue a written notice to require any person to attend an interview (Interview Notice). Non-compliance with the Interview Notice is a criminal offence. At the same time, the CO protects interviewees against self-incrimination for any statement made during such interview.

During the hearing, Nutanix and BT argued that the scope of this protection against self-incrimination covers not only the individuals but the companies themselves. Nutanix contended that certain statements made are inadmissible against the employer where the employee's conduct is sought to be attributed to

[2] CEAHR initially lodged a complaint with the Commission against the group of prestige/luxury watch manufacturers in July 2004. The Commission rejected CEAHR's complaint in July 2008 on the basis that there was insufficient interest to the EU in continuing the investigation. However, the GC annulled the Commission's decision in December 2010, on appeal by CEAHR, and the Commission opened an investigation into the watchmakers in August 2011. The Commission closed the investigation and again rejected CEAHR's complaint in July 2014, CEAHR brought a second appeal against the Commission's decision in October 2014, and it is this appeal which the GC has recently dismissed.

the employer, and the employee attended the interview and spoke on behalf of the employer. BT submitted that where the HKCC seeks to attribute the employee's conduct to the employer, the self-incrimination provision should cover the employer. In response, the HKCC argued that the statements made by the employee during the interview should not be regarded as statements made by the employer and therefore such statements remain admissible against the employer.

The presiding judge, Mr. Justice Godfrey Lam (the President of the Tribunal), held that the statements made during the interview are inadmissible only against the subject of compulsion, which is the person named on the Interview Notice, but not anyone else. Since the Interview Notices were each addressed to the named employee, it is the individual employee who can enjoy the privilege but not his/her employer. Nutanix and BT's applications were therefore rejected by the Tribunal.

Given the broad powers provided to the HKCC by the CO to summon any person to attend an interview, the privilege against self-incrimination would appear to offer companies little (if any) protection in relation to statements made during such interviews. There may be a stronger argument for a company to seek to exclude self-incriminating statements made if the Interview Notice is addressed to the company itself (and the company decides which employee to send to attend the interview). In particular, Mr. Justice Lam has confirmed that the word "person" in section 45 is, as a matter of definition, capable of meaning an undertaking, be it a company, partnership, unincorporated association or individual.

The case is scheduled for a 15-day trial before the Tribunal in June 2018.

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