SLAUGHTER AND MAY

Competition & Regulatory Newsletter

3 - 16 June 2020 / Issue 12

Quick Links

Advocate General advises the Court of Justice to uphold Commission fine against Lundbeck in relation to a number of 'pay-for-delay' agreements

On 4 June 2020 Advocate General (AG) Kokott recommended in her **opinion** that the Court of Justice (CJ) should dismiss, in its entirety, Lundbeck A/S' and Lundbeck Ltd.'s (Lundbeck)'s appeal against the General Court (GC)'s judgment in 2016, which had upheld the European Commission's 2013 infringement decision.

Background

In June 2013 the Commission fined Lundbeck, a Danish pharmaceutical group, c. €94 million in response to a number of 'pay-for-delay' agreements the company had entered into with generic manufacturers. These agreements concerned Lundbeck's antidepressant medical product 'citalopram' and imposed upon the generic manufacturers (Generics UK / Merck, Arrow, Alpharma and Ranbaxy) an obligation to delay the market entry of cheaper generic versions of citalopram in exchange for a financial sum.

In 2002, when the agreements were entered into, Lundbeck's patents protecting citalopram's active ingredient were about to expire in the EEA, but Lundbeck was still the holder of a number of secondary "*process patents*" relating to certain manufacturing processes. The Commission concluded that the agreements were restrictions of competition by 'object' and infringed Article 101 of the Treaty on the Functioning of the European Union (TFEU).

Lundbeck unsuccessfully appealed the Commission's decision to the GC, which upheld the Commission's decision.

Subsequently, Lundbeck appealed to the CJ. On 4 June 2020 the CJ **announced** that the AG handed down her opinion in this appeal.

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

Advocate General Kokott's opinion

Existence of potential competition

First, the AG assessed whether potential competition could exist between Lundbeck and the generic manufacturers. In the event that potential competition could not exist, there could be no agreement between competitors for the purposes of Article 101.

Lundbeck submitted that the GC was incorrect in failing to acknowledge that Lundbeck's patents gave rise to legal barriers to entry to the citalopram market, and therefore the generic manufacturers were not potential competitors.

In agreeing with the GC's judgment, the AG opined that Lundbeck's patents did not "*constitute insurmountable barriers to the entry*" to the citalopram market. The AG considered that uncertainty in regards to the validity of patents is a "*fundamental characteristics of the pharmaceutical sector*" and, therefore, generic manufacturers can be regarded as potential competitors to patent holders where they have a "*firm intention* […] *to enter the market*" and a willingness to risk infringement proceedings for breach of any associated intellectual property right. Therefore, the AG found that the generic manufacturers were potential competitors of Lundbeck.

Second, the AG considered Lundbeck's assertion that as the generic manufacturers did not have a marketing authorisation (MA) at the point when the agreements were entered into, they could not be considered potential competitors to Lundbeck. Agreeing with the position taken by the GC, the AG stated that precluding the existence of potential competition for all generic manufacturers without market authorisations would amount to precluding any competition and "*would run completely counter to the effectiveness of Article 101 TFEU*" as future market entrants could be constrained easily by 'pay-for-delay' agreements. This is because, in summary, if future market entrants are not regarded as potential competitors solely because they do not yet have an MA, their entrance to the market may be restricted prior to competition law applying, resulting in no actual competition ever materialising. The AG concluded that the generic manufacturers were potential competitors to Lundbeck.

Restrictions of competition by object

Lundbeck also contended that the agreements were not restrictions of competition by object, stating that agreements which impose restrictions, in relation to intellectual property rights, analogous to those they could have obtained through a court ruling cannot, fundamentally, be considered harmful to competition. Instead, it is the patent holder's prerogative to stop infringing products from reaching the market, and therefore 'pay-for-delay' agreements are a mere reflection of this. However, the AG once again agreed with the GC's judgment.

In considering the above argument, the GC concluded that while the agreements did indeed contain restrictions which could potentially fall within the scope of Lundbeck's patent rights, these could only have been enforced via court rulings, and it cannot be assumed that such claims would have been successful. Additionally, the GC found that the agreements went "*beyond the scope of* [Lundbeck's] *patent rights*", as Lundbeck, by virtue of the process patents, was not entitled to enter into agreements

to exclude potential competitors from entering the market in exchange for a financial sum (rather than e.g., from using the patented production process).

The AG concluded that the GC had not acted in error in reaching its conclusion. Additionally, she noted, among other things, that "*at risk*" market entries are part of normal competition in industries where exclusive rights to technologies and/or products exist, and that, generally, patent settlement agreements will have as their object a restriction of competition if the value transferred from the patent holder cannot be explained by anything other than the parties displaying a common commercial interest to not engage in competition.

Therefore, the AG found that the agreements should be classified as restrictions of competition by object.

Fines

Finally, the AG recommended that the CJ should uphold the GC's judgment to uphold the fines imposed onto Lundbeck by the Commission, both as a matter of principle and as regards their method of calculation.

Other developments

Merger control

European Commission conditionally approves Elanco's acquisition of Bayer's animal health division

On 8 June 2020 the European Commission **announced** that it has decided to conditionally approve Elanco Animal Health Inc.'s acquisition of the animal health division of Bayer AG. The $7.6 billion acquisition would create the second largest animal health company globally.

Elanco **announced** its proposed acquisition in August 2019 and notified the case to the Commission on 14 April 2020. The Commission's Phase I investigation focused on the market for pharmaceutical products for pets and livestock which encompasses a wide range of products that help to prevent or treat a variety of animal diseases and disorders. Although the proposed transaction raised no competition concerns in respect of the majority of the products supplied by both Elanco and Bayer, the Commission's investigation found that the originally notified transaction would have raised competition concerns in a number of countries in the EEA and UK in relation to otitis products used to treat ear infections in pets, as well as several types of antiparasitic drugs for cattle, sheep and household pets.

To address the Commission's concerns, Elanco offered to divest, to one or more suitable purchasers, Elanco or Bayer's overlapping products relating to otitis and antiparasitic drugs in the EEA and UK, including all the necessary assets such as applicable licences, contracts, and brands, as well as relevant studies and data. The Commission is satisfied that the proposed commitments fully address its concerns and has granted approval on the basis of full compliance with these commitments.

Antitrust

Chinese Court awards damages in Tencent AUCL data rights case

On 2 June 2020 China's Hangzhou Internet Court **awarded** Tencent RMB 2.6 million (approximately £328,000) in a lawsuit concerning data rights in relation to the Tencent's popular messaging, social media and mobile payment app, WeChat, under the Chinese Anti-unfair Competition Law (AUCL).

The defendants were two technology companies that assisted its customers in WeChat marketing efforts by automatically controlling multiple accounts and collecting individual WeChat users' data. The data was stored outside of WeChat on servers held by the companies. Tencent alleged that such use of data taken from WeChat breached the AUCL, as the defendants obstructed normal operations of online services provided by Tencent (Article 12 AUCL) and contravened laws and business ethics (Article 2 AUCL).

The Court ruled that, when deciding whether the unauthorised use of data constituted unfair competition for the purposes of the AUCL, the key issue was whether such use was destructive. Whilst Tencent had ownership and usage rights over the overall data resources on WeChat, its rights to individual WeChat end-users' data was limited. However, the Court found that the defendants' acts hampered the information security of WeChat users, and hence their trust in WeChat. Accordingly, the Court ruled that the use of the data was indeed destructive, undermining the trust of end-users and so harming Tencent's competitiveness as regards the overall data collected through use of WeChat.

This case sheds light on the PRC Courts' stance in connection with data rights that may be relevant for future disputes or enforcement actions under the AUCL or the Anti-Monopoly Law, which is an increasingly important area given the prominence of the online economy and technology sector in China.

CMA disqualifies a former director of two pharmaceutical companies

On 4 June 2020 the UK Competition and Markets authority (CMA) **announced** that it has accepted undertakings, which have equivalent legal effect to five-year disqualification orders, from Amit Patel following his admission to participating in two separate market-sharing agreements while a director at Auden McKenzie (Pharma Division) Limited and Amilco Limited. The disqualification undertakings will run concurrently and will prevent Patel from holding a directorship at any company for 5 years until 13 July 2025.

A CMA investigation into agreements affecting the supply of nortriptyline, an NHS prescribed drug to relieve symptoms of depression, found that Auden McKenzie and another pharmaceutical company had shared out between them the supply of the drug to a large wholesaler between September 2014 and May 2015. On 4 March 2020 the CMA fined Auden McKenzie £1.8 million for its role in the market-sharing agreement (see our previous **edition** of the newsletter for more detail).

Patel was also the sole director at Amilco, having held this directorship since 2013. Patel admitted that from March to October 2016 Amilco, along with another pharmaceutical company, agreed to stay out of the UK fludrocortisone market. Fludrocortisone is a prescription-only medicine to treat Addison's Disease. The CMA has alleged that this agreement enabled the market-leader, Aspen, to maintain its position as

sole supplier in the UK and gave it the opportunity to increase prices charged to the NHS by up to 1800 per cent. In exchange, Amilco received a 30 per cent share of the increased prices that Aspen was able to charge. Aspen, however, in August 2019 already admitted its part in the agreement and agreed to pay £8 million in compensation to the NHS.

On 15 June 2020 the CMA **announced** that it had accepted disqualification undertakings from two former estate agent directors after the CMA found that they had participated in an illegal price fixing cartel with two other local estate agents. These disqualifications bring the total number of disqualifications secured by the CMA to 18, after it began actively using its power in December 2016.

Brussels	London	Hong Kong	Beijing
T +32 (0)2 737 94 00	T +44 (0)20 7600 1200	T +852 2521 0551	T +86 10 5965 0600