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The Price of Health – A Review of key Competition Law Decisions in the Pharmaceutical Sector

The enforcement of EU competition law on pharmaceutical companies following the European Commission's 2009 inquiry into the pharmaceutical sector

The European Commission ("Commission") is known to keep a keen eye on the pharmaceutical sector. To that end, the Commission has adopted numerous policies and initiatives applicable to the pharmaceutical sector, and has called upon National Competition Authorities in the EU ("NCAs") to take similar actions. These measures are aimed at providing European patients with safe, effective and affordable medicines. This Newsletter gives an overview of noteworthy competition law enforcement actions taken by the Commission and the NCAs since 2009.

Background

When the Commission in 2008 had reasons to believe that effective competition in pharmaceutical markets in Europe may be impeded, it carried out an extensive sector inquiry into competition in the pharmaceutical sector. In its final report on the sector inquiry published in 2009, the Commission identified several shortcomings, including delays in the market entry of generic drugs and declines in the number of novel medicines reaching the market.[1] According to the Commission, these deficiencies stifle innovation, leading to higher drug prices and an overall reduction of choice between different medicines. In order to find a cure for these ailments the Commission announced that it would intensify its scrutiny of the pharmaceutical sector under EU competition law rules, especially as regards agreements between originator and generic drug companies. In addition, the Commission urged NCAs to implement measures that facilitate generic uptake and improve price competition.

A follow-on report from the Commission published earlier this year reviews competition law enforcement and market monitoring measures across the EU in the period from the completion of the sector inquiry in 2009 to 2017.[2] Needless to say, the Commission made good on its promise to put the competition law screws on the pharmaceutical sector.

In the reported period, the Commission and the NCAs adopted 29 antitrust decisions against pharmaceutical companies, imposing sanctions with fines totaling over EUR 1 billion, or accepting binding commitments to remedy anti-competitive behavior.[3] In addition, there were more than 100 investigations that did not lead to an intervention decision. Over 20 cases of possible antitrust infringements involving pharmaceuticals are currently being examined. At the heart of most cases is the often controversial interplay between competition law and intellectual property rights. The most widespread type of competition concerns leading to intervention decisions were abuses of dominance (45% of the cases). Other concerns were associated with restrictive agreements between companies. These include restrictive horizontal agreements between competitors such as pay-for-delay agreements (31%), outright cartels, such as bid rigging (17%), and vertical agreements, such as clauses prohibiting distributors from promoting and selling products of competing manufacturers (17%).

In the relevant period, the Commission reviewed more than 80 transactions under its merger control regime. Competition concerns were detected in 19 merger cases, which were cleared only after the companies offered to modify the transaction.

Patent settlement agreements

One prominent enforcement focus were the so called "pay-for-delay agreements", often

[1] Commission, Sector Inquiry Final Report, 08/07/2009.

[2] Commission, Competition Enforcement in the Pharmaceutical Sector (2009-2017), 28/01/2019.

[3] See the complete list of all 29 cases.

concluded to settle patent disputes at the end of the IP lifecycle of an originator product. Patent settlement agreements ("PSAs") are a legitimate means to conclude patent disputes. However, where PSAs are used to restrict or delay market entry of generics, they create negative effects on competition. Since 2009 the Commission has been monitoring PSAs between originator and generic companies, summarizing its findings in regular reports.[4] Furthermore, the Commission imposed fines in two seminal infringement decisions involving PSAs, namely *Lundbeck* and *Perindopril (Servier)*. In both cases the companies challenged the decisions before the General Court ("GC"). The GC already handed down its judgments, which are currently under appeal before the European Court of Justice ("CJEU"). At a national level the UK NCA's *Paroxetine* decision lead to a fine of EUR 56 million. It was appealed before the UK courts, who referred the case to the CJEU for a preliminary ruling.[5]

Lundbeck concerned agreements between the originator Lundbeck and four competing generic companies. The agreements provided for payments of EUR 67 million and aimed to prevent the launch of generic versions of Lundbeck's blockbuster Citalopram after patent expiry. Indeed, Lundbeck was able to shield Citalopram from competing products and preserved its sales price at the established level. Consequently, the Commission imposed fines of EUR 94 million on Lundbeck and EUR 52 million on the generic companies.[6]

The GC upheld the Commission's findings, confirming that pay-for-delay agreements are akin to market sharing. This is a restriction "by object" and thus constitutes a serious infringement. The GC confirmed that PSAs must be compatible with competition law rules. Furthermore, the GC concluded that Lundbeck and the generic companies were potential competitors, because even though patent protection for Citalopram still existed at the time the PSAs were concluded, the generic companies did not consider the patents to be an insurmountable market entry barrier. The GC based this conclusion on the fact that the generic companies had already made substantial investments to enter the market and that some of them had even entered several national markets "at risk".[7]

With regard to reverse payments by Lundbeck to the generic companies, the GC stated that such payment in itself does not infringe competition law, provided it is linked to the strength of the patent and not disproportionate. The size of the payment therefore indicates whether it is the strength of the patents or indeed the payment which causes the exclusion of competitors from the market or reduces the incentives to seek market entry.

Similar to *Lundbeck*, in *Perindopril (Servier)* the Commission found that the PSAs Servier concluded with five generic companies aimed to protect Servier's bestselling blood pressure medicine Perindopril from price competition by generics. The Commission qualified the PSAs as restricting competition "by object" and imposed fines totaling EUR 428 million on the companies involved. The Commission also found that Servier had abused a dominant market position on the market for Perindopril.[8] While the GC upheld the Commission's assessment that the PSAs constitute a "by object" restriction, it rejected the Commission's narrow market definition and annulled the Commission's finding of an abuse of market power by Servier. As a consequence, the GC reduced the total fines to EUR 315 million.[9]

Excessive prices

High and non-transparent drug prices set by pharmaceutical companies have been repeatedly called out as a problem for European healthcare systems. In an attempt to tackle this issue, there has been an uptake of cases against dominant pharmaceutical firms for charging unfairly high prices. Particularly noteworthy is the case against Aspen. The Italian NCA charged Aspen with a fine of EUR 5 million for excessive pricing, because Aspen abused its dominant position in markets for live-saving cancer treatments to impose price increases of 300-1,500%. Aspen was also said to apply aggressive tactics in price negotiations with the Italian Medicines Agency.[10] The Commission picked up the slacks and opened a formal investigation into similar concerns against Aspen's conduct.[11] So far, investigations by the Commission and

[4] Commission, 8th Report on the Monitoring of Patent Settlements, 09/03/2018.

[5] CJEU, Case C-307/18.

[6] Commission, Decision of 19/06/2003, Case AT.39226.

[7] GC, Judgment of 08/09/2016, Case T-472/13, currently under appeal before the CJEU, Case C-591/16 P.

[8] Commission, Decision of 30/09/2016, Case AT.39612.

[9] GC, Judgment of 12/12/2018, Case T-691/14 (only available in French), currently under appeal before the CJEU, Case C-176/19 P and Case C-201/19 P.

[10] L'Autorità Garante della Concorrenza e del Mercato ("AGCM"), Decision of 29/09/2016, Case A480.

[11] Commission, Opening of Proceedings on 15/05/2017, Case 40394. The investigation covers all of the EEA except Italy, because the Italian NCA already adopted an infringement decision against Aspen.

NCAs on excessive drug prices only concerned generic molecules. However, as recently stated in an OECD roundtable, neither Commission nor NCAs outright exclude the possibility to also investigate originator molecules.[12]

Coordination against off-label use

An example for another type of pharma specific coordination is the Italian investigation of *F. Hoffmann-La Roche and Others*. The proceedings concerned Hoffmann-La Roche's Lucentis, which is authorized to treat eye diseases, and Novartis' oncology medicine Avastin, which can be used off-label to treat eye diseases and is often preferred over Lucentis due to lower sales prices. According to the Italian NCA, the companies agreed to actively discourage the off-label use of Avastin for eye diseases, so that sales in that indication would not be cannibalized from the more expensive Lucentis. To achieve this goal, the companies campaigned publicly that the off-label use of Avantis was not safe. The Italian NCA fined the companies over EUR 90 million each.[13] The companies appealed the decision to Italian courts, which referred the case to the CJEU. The CJEU confirmed that the contested practice constituted a "by object" restriction.[14]

Denigration of generic medicines

Three investigations of the French NCA lead to fines against dominant firms for strategically disseminating incomplete and misleading information to healthcare professionals about the safety and efficacy of generic products.

In *Plavix*, Sanofi-Aventis abused its dominant position on the French market for Clopidogrel, the active substance of Plavix and the generic Clopidogrel Winthrop, which are both marketed by Sanofi-Aventis. The company launched a communication strategy to mislead physicians and pharmacists into refraining from generic substitution of Plavix. The EUR 41 million fine was upheld by the French courts.[15]

In *Buprenorphine*, Schering-Plough, its parent company MSD and supplier Reckitt Benckiser were fined EUR 16 million for granting kick-backs to practitioners for dispensing Subutex instead of generic versions of Buprenorphine.[16]

In *Durogesic*, Janssen-Cilag and its parent company Johnson & Johnson were fined EUR 25 million for training a specialist sales team to denigrate generics and publishing newsletters and press releases disparaging generic versions of Durogesic.[17]

Conclusions

Rigorous competition law enforcement in the pharmaceutical sector is here to stay. Pharmaceutical companies in Europe are therefore well advised to not only follow the decision practice of the Commission, but take note of key decisions adopted throughout Europe, and make adjustments to existing company practices as necessary to adhere to the requirements of EU competition law. Especially in light of the fact that most of the challenged practices are qualified as "by object" restrictions of competition, there will be little to no margin for discretion.

Some of the aforementioned decisions address anti-competitive practices that had previously not been subjected to EU competition law. The precedents indicate that neither Commission nor NCAs shy away from tackling anti-competitive behavior in the industry that has not yet found its way into standard compliance rules. As appeals on some cases are still pending, companies are required to keep a close eye on future developments in the sector to stay on the safe side.

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[12] OECD, Excessive Pricing in Pharmaceutical Markets, 03/12/2018, para. 102.

[13] AGCM, Decision of 27/02/2014, Case I760.

[14] CJEU, Judgment of 23/01/2018, Case C-179/16.

[15] Autorité de la Concurrence, Decision of 14/05/2013, Case 13-D-11, and related judgments.

[16] Autorité de la Concurrence, Decision of 18/12/2013, Case 13-D-21, and related judgments.

[17] Autorité de la Concurrence, Decision of 20/12/2017, Case 17-D-25.