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The Pharmaceutical Sector in the Focus of Competition Law – the Latest Developments in the new Commission Report

The European Commission has published its new report on competition law enforcement in the pharmaceutical sector

On 26 January 2024, the European Commission ("Commission") has published an updated report on competition law enforcement between 2018 and 2022, at EU and national level, in the pharmaceutical sector ("2024 Report").[1] The 2024 Report is an interesting read as it not only outlines recent decisions and antitrust investigations, but also clarifies the application of EU competition law to novel issues in pharmaceutical markets. The pharmaceutical industry therefore has to adapt compliance rules accordingly and take the indirect guidance on board to avoid fines. On a side note, the 2024 Report continues to give an easy-to-read overview on the specifics of the pharmaceutical industry and hence the regulatory framework in which a competition law assessment has to take place.

Background

In no other sector is the importance of antitrust law as clear as in the heavily regulated pharmaceutical sector: Since the Commission's sector inquiry in 2009[2], it is a clear policy goal to safeguarding patient's access to affordable and innovative essential medicines and protect the healthcare systems from excessive costs also by competition law enforcement.

The Commission as well as National Competition Authorities ("**NCAs**") have not shifted their focus away from the industry, but continue to monitor business practices in the pharmaceutical, health services and medical devices markets very closely. While enforcement activities continue to focus on practices that hinder or delay the market entry of generic medicines after a loss of exclusivity by the originator, there are also novel practices such as excessive prices for generic niche products, predatory prices, disparagement campaigns to the detriment of generic or biosimilar competitors or the abuse of the patent system that were subject to scrutiny or fines, in particular on national level. The Commission also reflects on its merger control decisions in the sector. Out of the 5 problematic proceedings in the review period, 4 could eventually be cleared after the parties offered commitments suitable to eliminate the Commission's concerns on price increases, insufficient access to innovative medicines and restrictions on innovation.

The 2024 report is an update to the overview that the Commission gave to the European Parliament in 2019 to inform about enforcement in the sector following its 2009 sector inquiry ("**2019 Report**")[3]. While the 2019 Report covered on developments in the time period from 2009 to 2017, the 2024 Report now covers the years 2018 to 2022.

The 2024 Report once again takes a holistic view and outlines not only case law concerning behavioral antitrust infringements, but also deals with the regulatory framework, competition law during the Covid 19 pandemic, and the proposal for new pharmaceutical legislation. This newsletter, however, only focuses on selected issues on the report's summary on enforcement activities by European competition authorities in the review period.

Anti-competitive practices under scrutiny

Between 2018 and 2022, the Commission and the NCAs adopted 26 antitrust decisions against pharmaceutical companies, imposing

[1] Commission, Update on Competition Enforcement in the Pharmaceutical Sector (2018-2022), 26/01/2024.

[2] Commission, Pharmaceutical Sector Inquiry Final Report, 8/7/2009.

[3] Commission, Competition Enforcement in the Pharmaceutical Sector (2009-2017), see also Commeo Newsletter of 10/06/2021.

fines totaling more than EUR 780 million, or accepting binding commitments to remedy anti-competitive behavior.[4] In addition, the Commission and NCAs investigated more than 70 other cases, of which 40 did not lead to an intervention decision and 30 are still pending.

The anti-competitive practices investigated included (i) the misuse of the patent procedures and abusive litigation to extend patent exclusivity; (ii) pay-for-delay agreements; (iii) the disparagement of a competitor's products to hinder the uptake of competing products and (iv) excessive prices charged for off-patent medicines.

Patent misuse and vexatious litigation

Otherwise legitimate patent conduct by a dominant undertaking may under certain circumstances constitute an abuse of dominant position in violation of Art. 102 TFEU. In October 2022, the Commission came to the preliminary conclusion that Teva may have abused its dominant position in the markets for a medicine for multiple sclerosis in several Member States to hinder market entry and competition for its glatiramer acetate medicine Copaxone.[5] One of the potentially abusive conducts is the misuse of patent procedures. Teva is alleged to have filed successive divisional patent applications before the European Patent Office with largely overlapping content. When competitors wanted to take legal action against this (to clear the path for market entry), Teva withdrew its parent patent application but left the divisional patents pending. As a result, Teva's competitors could have been forced to legally challenge essentially similar Teva patent claims multiple times with the result that legal uncertainty was artificially prolonged to the benefit of Teva and market entry of generic or generic like medicines was effectively blocked or delayed for example through interim injunctions.

In exceptional circumstances, where a dominant undertaking's legal action is objectively baseless, the practice of "vexatious litigation" may constitute an abuse of dominance. The Spanish NCA assumed such an abuse in the case of the pharmaceutical company Merck Sharp & Dohme GmbH ("MSD").[6] MSD enjoyed patent protection for the first vaginal contraceptive ring from 2002 to 2018. When its competitor Insud Pharma launched an alternative patent protected vaginal ring (named Ornibel) on the market in 2017, MSD filed legal action claiming patent infringement before a Spanish court and sought *inter alia* interim measures. The court ruled in favor of MSD and effectively halted the manufacture and sale of the Ornibel ring in Spain. The Spanish NCA considered that MSD deployed a strategy to mislead the court to hinder the market entry of a competitor by withholding relevant factual and technical information and providing misleading information to the court. The Spanish NCA regarded this as an attempt by MSD to prevent effective competition through legal measures and not to protect its patent. The NCA imposed a EUR 38,93 million fine on MSD.

Pay-for-delay agreements

Pay-for-delay agreements remain both at the Commission's and NCA's focus. Pay-for-delay agreements entered into between originator and generic pharmaceutical companies are agreements by which the generic company restricts or delays its independent entry onto the market in exchange for significant benefits transferred from the originator. In other words, the allegation is that the originator does not *bona fide* settle an imminent or ongoing patent dispute with a generic company, but pays the generic company for staying outside of the market for a certain period of time (so-called "pay-for-delay agreements"). Such agreements can infringe both, Art. 101 TFEU and Art. 102 TFEU.

In January 2020, the CJEU issued its first ruling regarding concerning pay-for-delay agreements after referral from the UK Competition Appeal Tribunal. The CJEU concluded that pay-for-delay agreements have the object of restricting competition when it is "*plain from the analysis of the settlement agreement concerned that the transfers of value provided for by it cannot have any explanation other than the commercial interest of both the holder of the patent and [generics company] not to engage in competition on the merits*".[7]

In the latest Commission case concerning pay-for-delay agreement, the *Cephalon* case, the General Court confirmed the Commission's fine decision of November 2020 on Teva.[8] The litigation concerning the Commission' Servier decision is still pending before the Court of

[4] See the complete list of all 26 cases.
[5] Commission, AT.40588, Press Release of 10/10/2022.
[6] Comisión Nacional de los Mercados y la Competencia, Decision of 21/10/2022.
[7] CJEU, Judgment of 30/01/2020, Case C-307/18 – 'Generics UK judgment'.
[8] General Court, Case T-74/21, Judgment of 18/10/2023.

Justice. Here, the Commission not only fined the companies for infringing Art. 101 TFEU but also found that Servier's practices were an abuse of dominance under Art. 102 TFEU.[9]

Disparagement cases

In the last years, in particular NCAs have increasingly investigated anti-competitive disparagement practices. Already in 2018, the CJEU ruled that companies may not collude to disseminate, in a context of scientific uncertainty misleading information relating to adverse reactions resulting from the off-label use of one pharmaceutical with a view to reducing the competitive pressure it exerts on another product.[10] This constitutes a restriction "by object" and therefore a violation of Art. 101 TFEU.

The French NCA, a pioneer in this respect, fined several originator companies for disparagement of their generic competitors as abuse of a dominant position.[11] Notably, in 2020, the French NCA fined Novartis, Roche and Genentech for a total of EUR 444 million finding again – not an infringement of Art. 101 TFEU – but an abuse of a collective dominant position of these three companies aiming at preserving the market position and the price of the pharmaceutical Lucentis by curbing the off-label use of Avastin. The NCA established that Novartis disparaged Avastin, since it unjustifiably exaggerated the risks associated with its off-label use in comparison with Lucentis for the same purpose.[12] The Paris Court of Appeal annulled the NCA's decision, ruling that no anti-competitive practice had been established against the three undertakings.[13] An appeal against this judgment is currently pending before the Court of Cassation. The Belgian NCA followed the same reasoning and imposed a fine of EUR 2,78 million on Novartis for abusing its collective dominant position held together with the Roche group.[14]

In the already mentioned investigation against Teva regarding Copaxone, the Commission also expressed concerns about a disparagement campaign targeting healthcare professionals and spreading doubts about the safety efficacy of Teva's competing medicine. Also the Commission investigates the disparagement allegations under Art. 102 TFEU, i.e. the abuse of a dominant position.

Abusive rebates and predatory pricing

Dominant pharmaceutical suppliers must ensure that the discounts they give do not amount to an abuse of their dominant position which is the case if those discounts hinder competitors to grow or even exclude competitors from the market. Notably, in 2019, the Dutch NCA launched an investigation into the discounts that AbbVie had offered hospitals for its drug Humira. The patent on this drug had expired and other drug manufacturers produced and marketed biosimilars of Humira. AbbVie's discount scheme stipulated that only hospitals that would continue to use Humira for all of their patients and therefore not switch to a biosimilar would receive the discount. The NCA concluded that AbbVie, as the former patent owner, had attempted to make it harder for biosimilar manufacturers to enter the market. The NCA closed its investigation after AbbVie submitted appropriate commitments.[15]

Excessive pricing

The NCAs and the Commission have been investigating several companies imposing excessive prices by abusing their dominant position.

Notably, the Commission launched its first excessive pricing investigation directed against Aspen. It followed the Italian authority that had already imposed a fine on Aspen back in 2006 for excessive prices for the same drugs sold in Italy. The Commission procedure was closed without fines following Aspen's very comprehensive commitment to significantly reduce prices for a period of 10 years. Following the criteria established in the *United Brands* case, the Commission found that Aspen's high profit margins from the sale of its cancer medicines – compared to the profit levels of similar companies in the industry – could not be justified for instance by the need to reward significant innovation and commercial risk-taking.

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9 Commission, Decision of 9/7/2014, Case AT.39612 – *Perindopril (Servier)*.

10 CJEU, Judgment of 23/01/2018, Case C-179/16 F. *Hoffmann-La Roche Ltd*.

11 See Autorité de la concurrence, Decision of 14/05/2013 (Plavix); Decision of 18/12/2013 (Subutex), Decision of 20/12/2017 (Durogesic).

12 Autorité de la concurrence, Decision of 09/09/2020.

13 Cour d'appel de Paris, Judgment of 16/02/2023.

14 Autorité belge de la concurrence, Decision of 23/01/2023.

15 ACM, Press Publication of 24/09/2020.

Other anti-competitive practices

Finally, the NCAs have intervened against various other anticompetitive practices ranging from the fixing of resale prices ("RPM"), to coordination between pharmacies and pharmaceutical companies, to a vaccine cartel between two Belgian wholesalers.

Conclusions

The 2024 Report shows: The pharmaceutical sector remains under strict competition law scrutiny by the Commission and the NCAs, that will not turn a blind eye. The European competition authorities are dedicated to use EU competition law and merger control rules to ensure affordable and easy access to medicines for patients while protecting Member States' healthcare systems, and therefore the public, from excessive costs.

Some of the key decisions outlined in the 2024 Report are novel cases that have not yet found their way in standard compliance programs. This needs to be remedied by all companies active in the pharmaceutical sector. Companies should also remain alert that there is no *numerus clausus* for illegal behavior. This is particularly true for dominance cases where case law is in a constant state of flux.

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