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GLOBAL COMPETITION REVIEW

The European, Middle Eastern and African Antitrust Review 2019

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GLOBAL COMPETITION REVIEW

European Union: Pharmaceuticals

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This survey covers the main developments in the pharmaceutical sector in the European Union over the period 2017–2018.[1] This past year has been rich in developments, the most noticeable of which were the confirmation of the competition authorities' interest in excessive pricing cases and the Court of Justice of the European Union (CJEU) landmark judgment in the *Hoffmann-La Roche* case. Patent settlement appeals against the European Commission (Commission) and the UK Competition and Markets Authority (CMA) decisions have continued, with significant judgments expected in 2018–2019, which will help clarify the law. On the merger control front, the treatment of innovation in merger cases has continued to be an important topic.

Patent settlement cases

Since its sector inquiry into the pharmaceutical sector closed 10 years ago, the Commission has continued to monitor settlements entered into between pharmaceutical companies that are intended to resolve disputes on the validity of patents. The Commission's concern regarding these types of agreements is that they could be used by the makers of originator drugs to pay generics not to enter the market and are in essence pay-for-delay agreements rather than good faith settlements of genuine legal disputes.

The Commission's latest report on the monitoring of patent settlements was published on 9 March 2018 and covers the period from January to December 2016.[2] The report is very similar in shape and form to the previous reports. It reaffirms the Commission's commitment to subject so-called B.II settlements[3] to the highest degree of antitrust scrutiny,[4] but falls short of providing guidance as to what is an acceptable settlement. In practice, to remain on the safe side, pharmaceutical companies should primarily consider early-entry types of settlements, at least until the EU courts provide more clarifications on the applicable test.

As regards the content of the report, the Commission found that the number of B.II settlements have stabilised at a low level and now represent only 11 per cent of settlements, as opposed to 24 per cent during the period covered by the sector inquiry (2000–2008).[5] This is only a relative drop, however: overall, the Commission identified four times more patent settlement agreements in 2016 (107) than the yearly average during the sector inquiry (24), so that the absolute number of B.II patents will also have risen during that time. In spite of this, the Commission has not initiated any new investigations in this area since 2011.

Indeed, since the sector inquiry, the Commission has taken two decisions finding that patent settlement agreements had been used to restrict competition, in the *Servier* and *Lundbeck* cases.[6] In both cases, the addressees have challenged the decision before the EU courts. The General Court presented a judgment in favour of the Commission in *Lundbeck* in September 2016,[7] but the case is now under appeal before the CJEU. In *Servier*, several hearings took place before the General Court of the European Union (General Court) in June and July 2017, and a judgment is expected in the course of 2018.

There are also ongoing proceedings before the Commission against a generic pharmaceutical company, Teva, which allegedly entered into an anticompetitive settlement agreement with Cephalon, another pharmaceutical company. Cephalon, which subsequently became a Teva subsidiary, owned the patents for the blockbuster sleep-disorder drug modafinil. When the primary patent expired, Teva entered the market with its generic version of modafinil. This prompted Cephalon to bring legal proceedings against Teva, alleging a breach of certain process patents which were still in force. The case was settled in the UK and in the US with a global agreement. Under the terms of the agreement, Teva agreed to keep its generic drug off the market in the EEA until October 2012, in exchange for a series of cash payments from Cephalon, as well as what the Commission refers to as 'various other agreements'.[8] Although proceedings were opened by the Commission in 2011, a statement of objections was only sent in July 2017.

Before the Commission had reached a decision in *Servier* in 2014, UK health authorities brought claims before the High Court in London seeking compensation for the alleged anticompetitive agreements between Servier and the generics.[9] The High Court is due to deal with certain preliminary issues in 2019.

Another UK court, the Competition Appeal Tribunal (CAT), is examining an appeal by GSK and several generic companies against a decision of the CMA finding that GSK had entered into anticompetitive agreements with generics manufacturers to delay their entry onto the market, and that this behaviour also amounted to an abuse of a dominant position by GSK. Noting that several of the issues raised by the case were subject to appeals before the EU courts in the *Lundbeck* and *Servier* cases, the CAT decided to refer certain questions to the CJEU for a preliminary ruling.[10] These questions are lengthy and worth reading in full, together with the CAT interim judgment on the facts. In summary, they cover the following points:

Potential competition

The CAT asked several questions to determine under which conditions an originator and a generic may be considered potential competitors, in particular in light of the existence of a dispute or injunction proceedings.

Restriction by object

The CAT asked several questions to determine whether a patent settlement agreement may be considered restriction by object, in particular in light of the existence of value transfers of different sizes and forms, including supply agreements between the originators and the generic company.

Restriction by effect

The CAT asked whether the finding of a restriction by effects depends on the likelihood of generic having won the litigation or, alternatively, on the likelihood that a less restrictive agreement would have been entered into.

Market definition

The CAT asked whether competition from generic drugs prior to their effective entry is to be taken into account when defining the market.

Abuse of dominance

The CAT asked several questions on the conditions under which one or several patent settlement agreements can constitute abuses of a dominant position.

These questions were sent to the CJEU at a time at which the latter is already examining Lundbeck's appeal and shortly before the General Court is to decide the appeal in *Servier*. This means that the next two to three years are likely to be rich in jurisprudence, which will hopefully provide the much-needed clarification on these issues.

Excessive pricing in the pharmaceutical sector

Although 'unfair pricing' is listed as a conduct that could amount to an abuse of a dominant position under the EU competition rules, competition authorities have traditionally been reluctant to pursue excessive pricing cases and many had failed on the facts. The leading EU judgment is *United Brands* from 1978.[11] Nonetheless, in the past couple of years, excessive pricing cases in the pharma sector have been one of the hallmarks of EU competition enforcement. The national competition authorities have led the way and issued groundbreaking decisions in Italy (*Aspen*) and in the United Kingdom (*Flynn/Pfizer*) in 2016. The Commission has followed suit by opening its own investigation into Aspen's practices in 2017, with the first-ever pure excessive pricing investigation.[12] Denmark is the latest member state to enforce competition law against excessive pricing.

Excessive pricing in court

On 7 December 2016, the CMA imposed a fine of £90 million on Pfizer and Flynn for charging unfair prices by an increase of 2,600 per cent (for end prices) in phenytoin sodium capsules.[13] This was the first decision of the CMA in a pure excessive pricing case. Pfizer and Flynn brought the decision before the CAT on 7 February 2017.[14]

The core of the CMA's finding that the prices charged by Pfizer and Flynn were excessive was that those prices significantly exceeded a reasonable rate of return (defined as a 6 per cent return on sales), and were significantly higher than previous levels. In its decision, the CMA argued that the extent of the excess above a reasonable rate of return was such as to make the prices unfair in themselves.

In the course of the hearing before the CAT during November 2017, the CMA sought to emphasise a secondary position, namely that the prices were excessive when compared with the previous price levels of the same drug. Pfizer argued that the CMA wrongly failed to assess whether Pfizer's prices were excessive by comparison to the prices of other similar products, specifically phenytoin sodium tablets, which were not only higher than those of phenytoin sodium capsules but had also already been subject to a significant decrease following intervention by the Department of Health. Pfizer contended that this comparison showed that Pfizer's prices were not unfair when compared to competing products. Pfizer also argued that the CMA had failed to investigate the economic value of the product to patients and thus had failed to show the prices were excessive.

The CMA has also opened investigations into *Concordia* and *Actavis*. In the latter case, the CMA issued a statement of objections alleging that Actavis charged an excessive and unfair price in relation to the supply of hydrocortisone tablets in the UK.[15] In particular, according to the CMA, Actavis increased the price of the 10 mg tablets by over 12,000 per cent and of the 20 mg tablets by nearly 9,500 per cent, compared to the branded version of the drug.[16] The CMA is expected to issue its decision in the second quarter of 2018.

CD Pharma in Denmark

On 31 January 2018, the Danish Competition Council (DCC) found that the pharmaceutical distributor CD Pharma had abused its dominant position by charging unfair prices.[17] Between 28 April and 27 October 2014, CD Pharma increased the price for Syntocinon from 45 DKK to 945 DKK. This meant a price hike of 2,000 per cent. Syntocinon contains oxytocin, an active substance used in the induction of labour during childbirth, which has been off-patent for many years. CD Pharma was found to hold a dominant position in the Danish market for oxytocin thanks to its exclusive agreement with the producer of Syntocinon.

The DCC's decision concluded that CD Pharma had imposed unfair prices upon Amgros, a wholesale buyer of medicines for Danish hospitals. The parallel importer Orifarm had won Amgros' tender for the supply of Syntocinon, but it was unable to provide the full amount of the medicine. For this reason, Amgros had to resort to CD Pharma as the only alternative supplier of Syntocinon in the market. As a result of the price increase, Amgros paid approximately 6 million DKK more than the original contract with Orifarm.

As in the *Pfizer/Flynn* and *Aspen* cases, the DCC based its analyses on the two limbs of the United Brands test.[18] It considered, first, that the difference between costs and selling prices was excessive, given CD Pharma's high profit margins of around 80 per cent. Second, the DCC found the price unfair both by itself and compared to competing products. The prices charged on Syntocinon were approximately 2,000 per cent higher than Amgros' two previous suppliers, Sobi and Novartis. The DCC also compared the price charged in Denmark with its neighbouring countries. CD Pharma was unable to convince the competition authority of the validity of its reasons to increase the price.

DCC ordered CD Pharma to refrain from using this practice in the future and submitted the matter to the State Prosecutor for Serious Economic and International Crime. The case has been appealed to the Competition Appeals Tribunal.

The Latvian Societies CJEU judgment

On 14 September 2017, the CJEU handed down a judgment in a preliminary ruling in a Latvian case concerning excessive pricing by collecting societies.[19] This case offered the court and AG Wahl an opportunity to examine the *United Brands* judgment. AG Wahl's Opinion contains a detailed overview of the criteria for excessive pricing, which offers helpful guidance. In particular, AG Wahl noted that there are a variety of different methods that could be deployed to determine whether a price is excessive. Given that there is no one test that can be used in all situations (eg, a cost-price test may not be useful when it comes to intangible goods like copyright music), and given each test has its own weaknesses, the proper approach is to 'combine several methods' where possible, to avoid errors and to reach a reliable conclusion.[20] AG Wahl considered that an abuse can be established where there is a 'sufficiently complete and reliable set of elements which point in one and the same direction', such that 'almost no doubt remains' that there was an abuse.[21] Both AG Wahl and the CJEU noted that a comparison between the prices

in different member states could be one of the tests used, provided that the reference member states are selected based on objective and appropriate criteria, taking account of demand side factors, and differences in purchasing power.[22]

It will be interesting to see how far the recent judgment of the CJEU has an impact on Pfizer's and Flynn's appeals in the UK and CD Pharma's appeal in Denmark.

Rebates in the pharmaceutical sector

In May 2017, the CMA issued a statement of objections against the pharmaceutical company MSD, alleging that it operated an anti-competitive rebate scheme for its medicine Remicade.[23] The CMA alleged that MSD abused its dominant position by implementing a rebate scheme that impeded the sale of biosimilar versions of Remicade. According to the CMA, the rebate scheme dissuaded Merck's customers from switching to cheaper alternatives of the medicine. The case is currently pending, and the CMA is expected to issue a final decision in 2018.

It remains to be seen how the CMA will factor in the recent *Intel* judgment[24] of the CJEU on rebates handed down on 9 September 2017, in which the Court ruled that the Commission (and the General Court) cannot consider rebates, and in particular loyalty rebates, as per se illegal. The CJEU stated that the Commission is required to show that a specific rebates scheme is capable of restricting competition before finding a company liable for abuse of a dominant position under article 102 TFEU. To do so, the Commission is required to examine all the relevant circumstances invoked by the dominant company. Finally, in connection with the assessment of actual foreclosure effects, the CJEU invoked the as-efficient competitor (AEC) test. The CJEU ruled that, if the AEC test is advanced as a justification by the dominant company, the Commission must assess in detail whether the rebates would prevent an 'as-efficient competitor' from competing with the dominant company.

Interestingly, in June 2016, the CMA closed an investigation into rebates applied to pharmaceuticals and confirmed that it will use the AEC test.[25]

Off-label use

On 23 January 2018, the Grand Chamber of the CJEU delivered its judgment in the *Hoffman-La Roche* case, which concerns the off-label use of the drug Avastin for the treatment of ophthalmological pathology in Italy.

Avastin was developed by Genentech, a US subsidiary of Roche. Genentech also developed the medicine Lucentis from related active substances. Lucentis was granted a marketing authorisation (MA) for the treatment of eye diseases, while the Avastin was granted an MA for oncological applications. A licence for the exploitation of Lucentis was granted to Novartis (shareholder of Roche), while Avastin was licensed to Roche. Despite the different MAs of the two products, an off-label use of Avastin for the treatment of eye diseases spread widely in Italy.

In 2014, the Italian competition authority found that Roche and Novartis had colluded to discourage the off-label use of Avastin and had a common interest in causing a shift in demand in favour of the more expensive Lucentis by disseminating information aimed at raising concerns regarding the safety of the off-label use of Avastin. As a result, the companies were fined approximately €90 million each.[26]

On appeal by Roche and Novartis, the Italian Council of State referred a series of questions to the CJEU, which covered, among others things:

- the market definition in the context of authorised and non-authorised medicinal products;
- the possible classification of the conduct in question as an ancillary restriction to the licence agreement; and
- whether such conduct, if proven, could amount to a restriction of competition by object.

With regard to the market definition question, the CJEU stressed that products manufactured and sold illegally could not, as a matter of principle, be viewed as substitutable or interchangeable with lawfully authorised products, in particular because of the risks involved for public health. Second, the CJEU stated that while EU rules on pharmaceutical products do not directly prohibit the off-label use of an authorised medicinal product or its repackaging, such activities are subject to strict conditions,[27] and that it is for national courts and pharmaceutical authorities, and not for competition authorities, to review off-label uses of medicinal products. It then concluded that the uncertainty as to the legality of the off-label use of a product is not enough to preclude it from being in the same market as another product. This means that where the conditions for off-label use are met, or where no unlawful off-label use has been established by the competent bodies, it is possible for authorised and off-label drugs to be part of the same market, provided of course they are effectively used for the same therapeutic indication.

With regard to the second question, the CJEU, in line with its analysis in the *MasterCard* judgment,[28] found that the conduct in question could not qualify as an ancillary restraint to the licensing agreement. The CJEU pointed out that the objective of the conduct, entered into several years after the licence, was to influence the behaviour of third parties, rather than to restrict the commercial autonomy of the licensing parties themselves.[29]

Finally, with regard to the question on the possible qualification of the conduct as a restriction by object, the CJEU confirmed that the concept of restriction of competition by object should be interpreted restrictively, and that the key criterion is whether the degree of harm displayed by the agreement is sufficient to obviate the need to look at its actual effects.[30] The CJEU also recalled that the object of an agreement must be analysed in light of its context, which means, in the pharmaceutical sector, that the assessment must take into account the EU rules on pharmaceutical products, including pharmacovigilance.[31] The CJEU thus assessed whether the conduct in question went beyond the parties' pharmacovigilance obligations. On this point, the Court noted that pharmacovigilance obligations normally weigh on the MA holder, and not on the company marketing a competing product, so the involvement of a competitor could indicate that the conduct had a different purpose.[32]

In addition, the CJEU pointed out that the information communicated to the public and to the various authorities could, if it did not satisfy the regulatory requirements laid down in Regulation 658/2007[33] (namely, being complete and accurate), be regarded as misleading if the purpose of that information (second condition of the test) was:

- to mislead the relevant authorities in order to obtain the inclusion of the adverse reactions to Avastin in the summary of product characteristics, so as to enable the MA holder to launch a communication campaign aimed at healthcare professionals, patients and other persons, with a view to exaggerating that perception artificially; and
- to emphasise, in a context of scientific uncertainty, the public perception of the risks associated with the off-label use of Avastin.[34]

The CJEU concluded that, given the characteristics of the pharmaceutical market, conduct found to pursue the objective of spreading such misleading information would lead to a reduction in demand and, consequently, of the competitive pressure exercised by the off-label product. It would therefore display a sufficient degree of harm to competition to constitute a restriction by object.[35] It now remains to be seen whether, on the facts, the Italian courts will find that misleading information was indeed communicated (the proceedings are still pending in Italy).

Beyond the specific facts of the dispute, the judgment is significant in that it is the first time that the court suggests to apply the concept of restriction by object to an agreement which (if the factual premises set out by the CJEU were subsequently to be confirmed by the national courts) aimed to disseminate allegedly misleading information about the safety of a medicinal product. While the judgment somehow echoes the decisional practice of the French Competition Authority, which has sanctioned a number of pharmaceutical companies for denigrating competing generic products,[36] it is worth noting that the CJEU's test for misleading in the present case appears to be more narrowly defined than the test in the French cases.

Competition law assessment of mergers in the pharma sector

In 2017–2018, the Commission reviewed nine transactions in the pharmaceutical sector.[37] While several of these transactions involved private equity firms and led to simplified proceedings, the Commission had the chance to provide additional guidance on the assessment of mergers in the pharmaceutical sector with the *J&J/Actelion* decision. In addition, several high-profile transactions in related sectors, including *Dow/DuPont* and *Bayer/Monsanto*, have provided additional information on the Commission's approach in tackling innovation issues.

Concerns around innovation

Since the Commission's decision in *Dow/DuPont* in March 2017,[38] there has been a great deal of discussion around the assessment of the ways firms innovate and the role this can have in merger review.

The importance of 'innovation' as a parameter of competition to be assessed under EU merger control law was already reflected in the Commission's horizontal merger guidelines published in 2004.[39] However, the risk identified in the Guidelines is that where entities merge and at least one of them has new products 'in the pipeline', their incentives to continue developing those products would be lessened and competition would be impeded.

In order to address this, the Commission (and the US FTC) has, in the past, examined whether a proposed merger creates an overlap between a product actively marketed by one of the parties and a pipeline product being developed by the other party (market-to-pipeline), or whether the parties developed pipeline products separately that would eventually compete on the market (pipeline-to-pipeline). Pipeline products include products at a relatively late stage of development, with a good chance of launch within two to three years.

In *Dow/DuPont*, the Commission went further in the way the impact of mergers on innovation is examined: the Commission did not focus on specific product overlap, but assessed the impact on innovation 'as a whole'. Putting it simply, the Commission found that Dow and DuPont would likely reduce their R&D budget post-merger, which would inevitably lead to a smaller number of new products brought to the market. To remedy this, the Commission ordered the divestiture of DuPont's global R&D organisation in pesticides.

Since then, the Commission has examined the importance of competition in innovation in its assessment of another large merger, *Bayer/Monsanto*.[40] In its decision to clear the transaction, the Commission imposed obligations on the companies to divest entire lines of research in order to address the Commission's concerns that innovation competition would be reduced.

In the pharmaceutical sector, the Commission has considered companies to have overlapping operations on the basis that both have innovative pipeline products. In *J&J/Actelion*,[41] it expressed concerns regarding the closeness of innovation competition between the parties on drugs to treat insomnia. The Commission saw the existence of a risk for innovation competition stemming from a possible discontinuation, delay or reorientation (eg, targeting specific therapeutic indications or patient groups within insomnia so as to make sure the two pipelines do not directly compete with each other).[42] J&J was required to divest itself of its interest in its own pipeline drug by granting another company a licence over the drug's development and waiving royalty rights on the sale of that drug in the EEA.

Sector inquiries in France and Spain

The French Competition Authority started a new inquiry into the pharmaceutical industry in November 2017.[43] This inquiry follows a previous sector inquiry, published in 2013, and aims at assessing whether the recommendations of the authority have been followed and how the French pharmaceutical sector has evolved in recent years. The inquiry investigates biological medicines and focus on two major subjects: the pharmaceutical distribution chain; and medicine pricing. With regard to the pharmaceutical distribution chain, the authority wants to review the role of intermediaries in price dynamics. With regard to medicine pricing, the authorities will examine, among other things, the beneficiaries of generic competition, the criteria used in the negotiation of reimbursable medicines, and the determination of prices in hospitals.

On 17 March 2017, the Spanish competition authority (CNMC) launched a sector inquiry into the wholesale supply and marketing of medicines in Spain.[44] In a preliminary finding, the CNMC had detected potential restrictions on competition arising from the functioning and structure of the Spanish market. The authority notes that the highly regulated sector needs to comply with the principles of necessity and proportionality to avoid introducing unjustified restrictions. The inquiry will analyse strategic behaviours of companies holding patents on innovative medicines that may restrict or delay the entry of generics. Moreover, the inquiry will analyse the highly regulated pricing system and the wholesale determination of margins. The CNMC will complement its analysis with the assessment of alternative mechanisms, namely centralised purchasing schemes and tender auctions. This inquiry follows a previous study from 2015 on the retail distribution of medicines in Spain.

The opinions expressed in this article are personal to the authors and do not necessarily represent the opinions of either White & Case LLP or any of its clients.

Notes

1 This review covers the period between September 2017 and April 2018.
2 European Commission, Eighth report on the Monitoring of Patent Settlements, 9 March 2018.
3 These are settlements featuring a restriction on the generic's commercial freedom and a value transfer from the originator to the generic, whatever its form.
4 Eighth report on the Monitoring of Patent Settlements, paragraph 17.
5 Ibid., paragraph 49.
6 Commission decision of 19 June 2013 in Case AT.39226 – *Lundbeck* and Commission decision of 9 July 2014 in Case AT.39612 – *Perindopril (Servier)*.
7 Case T-472/13, *Lundbeck A/S and Lundbeck Ltd v European Commission*, EU:T:2016:449.
8 See European Commission, Commission sends Statement of Objections to Teva on 'pay for delay' pharma agreement, Press Release IP/17/2063 of 17 July 2017.
9 HC-2011-000064 *The Secretary of State for Health and another v Servier Laboratories Ltd and others*, in the Chancery Division, High Court of Justice of England and Wales.
10 *Generics UK Limited and ors. v Competition and Markets Authority* [2018] CAT 4.
11 C-27/76, *United Brands v Commission*, ECLI:EU:C:1978:22.
12 See European Commission, Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines, press release of 15 May 2017 (IP/17/1323).
13 Decision of the Competition and Markets Authority of 7 December 2016 in Case CE/9742-13, Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK.
14 *Pfizer Inc. and Pfizer Limited v Competition and Markets Authority*, Case No: 1276/1/12/17; and *Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority*, Case No: 1275/1/12/17.
15 See press release of the CMA, available at https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs.
16 De-branded (genericised) drugs are not subject to price regulation in the UK.
17 Decision of the Danish Competition Council of 31 January 2018, CD Pharmas prissætning af Syntocinon. See also the press release of the competition authority: 'CD Pharma has abused its dominant position by increasing their price by 2,000 percent'.
18 Case C-27/76, *United Brands v Commission*, EU:C:1978:22, paras 250–252.
19 Case C-177/16, AKKA/LAA, EU:C:2017:689.
20 Ibid., Opinion of AG Wahl, paragraphs 36–45.
21 Ibid., Opinion of AG Wahl, paragraphs 54, 112.
22 Ibid., CJEU judgment, paragraphs 41–45; Opinion of AG Wahl, e.g. at paragraphs 39–41, 90–93.
23 See https://www.gov.uk/cma-cases/pharmaceutical-sector-alleged-discounts-offered-on-a-product.
24 C-413/14 P, *Intel v Commission*, EU:C:2017:632.
25 In June 2015, the CMA closed an investigation on discounts in the pharmaceutical sector and provided guidance to market participants in relation to the compliance of rebate and discount schemes with competition law, which would be relevant for subsequent investigations (see https://www.gov.uk/cma-cases/investigation-into-conduct-in-the-pharmaceutical-sector). The CMA press release with the relevant guidance is available at: https://assets.publishing.service.gov.uk/media/558c2743e5274a1559000004/ Pharmaceutical_sector_investigation_closure_statement.pdf.
26 AGCM, Provvedimento no. 24823 of 27 February 2017, Case I760 – *Roche-Novartis/Farmaci Avastin e Lucentis*.
27 Ibid., paras 57 and 58.
28 See C382/12 P, *MasterCard and Others v Commission*, EU:C:2014:2201, paras 8–90.
29 See *Hoffmann-La Roche* judgment, paras 72–73.
30 See *Hoffmann-La Roche* judgment, paragraph 78, C-67/13 P, *CB v Commission*, EU:C:2014:2204, paragraph 53.
31 Pharmacovigilance must be respected by MA holders, and imposes an obligation to supply the EMA, the Commission, and the member states with any new information relevant for the issuance of an MA and any other new information which might have an impact on the benefits and risks of the product.
32 See *Hoffmann-La Roche* judgement, paragraph 91.
33 Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No. 726/2004 of the European Parliament and of the Council, OJ L 155/10, 2007.
34 See *Hoffmann-La Roche* judgment, paras 93–95.
35 See *Hoffmann-La Roche* judgment, paras 92–93.
36 French Competition Authority Decision No. 13-D-21 related to practices implemented on the French market of the high dosage buprenorphine commercialised in town, 18 December 2013; French Competition Authority Decision No. 13-D-11 related to practices implemented in the pharmaceutical sector, 14 May 2013.
37 Commission decisions in Case COMP/M.8362 – *Lonza Group/Capsugel*, COMP/M.8385 – *Pillarstone/Famar*, COMP/M.8401 – *J&J/ACTELION*, COMP/M.8440 – *DuPont/FMC (Health And Nutrition Business)*, COMP/M.8483 – *Bain Capital Investors/Cinven Capital Management/ Stada Arzneimittel*, COMP/M.8522 – *Avantor/VWR*, COMP/M.8541 – *Thermo Fisher Scientific/Patheon*, COMP/M.8556 – *Carlyle/Gtcr/Albany Molecular Research*, COMP/M.8675 – *CVC/Teva's Women's Health Business*.
38 Commission decision of 27 March 2017 in Case COMP/M.7932 – *Dow/DuPont*.
39 Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings OJ C 31, 5 February 2004, pp 5–18, paragraph 38.
40 Commission decision of 21 March 2018 in Case COMP/M.8084 – *Bayer/Monsanto*; see European Commission, Commission clears Bayer's acquisition of Monsanto, subject to conditions, Press Release of 21 March 2018 (IP/18/2282).
41 Commission decision of 9 June 2017 in Case COMP/M.8401 – *J&J/Actelion*.
42 Ibid., paragraph 38.
43 See www.autoritedelaconcurrence.fr/user/standard.php?id_rub=662&id_article=3067&lang=fr.
44 https://www.cnmc.es/sites/default/files/editor_contenidos/Notas%20de%20prensa/2017/20170317_NP_Estudio_Medicamentos_eng.pdf

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Jérémie Jourdan is a local partner at White & Case Brussels and Paris. He returned to White & Case after spending two years at the European Commission in the Hearing Officers' team between 2010 and 2012.

His practice focuses on advising clients in antitrust and merger control proceedings. In recent years, he has been involved in several high-profile antitrust investigations before the EU Commission and courts. In the pharmaceutical sector, he represented a pharmaceutical company in the Commission sector inquiry of 2008. Since then, he has also been representing Les Laboratoires Servier, first before the Commission, and then before the General Court in the largest case to date concerning patent settlement agreements. The case involves the application of both articles 101 and 102.

James Killick
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James Killick led the firm's Global Pharmaceuticals and Healthcare practice from 2010-2014. He regularly advises leading pharmaceutical multinationals and the major US and EU industry pharmaceutical associations on EU and national law and policy affecting the pharmaceuticals sector.

His pharmaceutical practice covers competition law, including licensing and distribution issues, regulatory matters, intellectual property, data protection, and national implementation of EU measures, notably on pricing and reimbursement.

He has been involved in pleading a number of leading cases in the European Courts, including *Microsoft v Commission* (compulsory licensing; treatment of trade secrets), *Hanner* (Swedish retail monopoly on pharmaceuticals), *Pfizer v Council* (precautionary principle), *IMS Health* (compulsory licensing), and *Servier v Commission* (banning of pharmaceuticals).

He was actively involved in the European Commission's pharmaceutical sector inquiry, representing a major global company, and has spoken extensively on this topic.

Axel Schulz
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Axel Schulz advises on a broad range of EC and German competition law matters. He has particular expertise in the pharmaceutical industry, advising on competition law issues in the fields of distribution, co-marketing, licensing and other kinds of vertical and horizontal cooperation agreements.

He advised Almirall in their patent dispute with Boehringer Ingelheim, in which Boehringer agreed to remove its blocking positions and the European Commission investigation was closed. He also represented Nycomed in an investigation by the Commission, which was closed without making any finding that the company violated the law and without imposing any fine. In addition, Axel secured favorable judgments for Abbott in two Greek court cases initiated by Greek pharmaceutical wholesalers requesting large quantities of prescription medicines in order to export them. He has also represented GlaxoSmithKline in a number of cases before the European Courts in Luxembourg.

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A key feature of our practice is in handling matters of first impression relating to the cutting-edge, fast-moving area at the intersection between IP and antitrust in the pharmaceutical industry. Our work on behalf of pharmaceutical clients includes defense against challenges to 'reverse payment' patent settlement agreements, 'product-hopping', excessive pricing, claims of Walker Process fraud before the US Patent and Trademark Office, 'sham' IP enforcement and US Food and Drug Administration petitioning, and other allegations of improper conduct to delay or inhibit competition. In the EU, we have extensive experience litigating claims brought by antitrust authorities, both at EU and national level.

Strati Sakellariou-Witt
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Strati Sakellariou-Witt advises on European competition law and general European Union law questions. She has particular expertise in pharmaceuticals and life sciences, where she advises on competition law issues, including distribution, rebates, generic and biosimilar entry. Strati also advises pharmaceutical, biotech and life sciences multinationals on EU and national law and policy affecting the pharmaceuticals and veterinary medicines sector, including licensing and distribution issues, complex regulatory matters, intellectual property and national implementation of EU measures.

Strati successfully represented Pfizer and Abbott in abuse of dominance court proceedings in relation to parallel trade of pharmaceuticals. She also represents clients in merger control reviews, and has comprehensive experience in in-depth investigations which include negotiation of divestitures. Recently, she represented Zimmer Holdings, a world leader in musculoskeletal health solutions, in obtaining merger clearance from the European Commission for its US$13.35 billion acquisition of Biomet, Inc. This complex Phase II case was cleared two months prior to the official deadline.

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