

EUROPE, MIDDLE EAST AND AFRICA

ANTITRUST REVIEW 2020

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ANTITRUST REVIEW 2020

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Preface

Global Competition Review is a leading source of news and insight on competition law, economics, policy and practice, enabling subscribers to stay apprised of the most important developments worldwide.

GCR's Europe, Middle East and Africa Antitrust Review 2020 is one of a series of regional reviews that deliver specialist intelligence and research to our readers – general counsel, government agencies and private practitioners – who must navigate the world's increasingly complex competition regimes.

Like its sister reports covering the Americas and the Asia-Pacific, this book provides an unparalleled annual update from competition enforcers and leading practitioners, on key developments in both public enforcement and private litigation.

In addition to updates on the European Commission, Cyprus, Denmark, France, Germany, Greece, Norway, Romania, Portugal, Russia, Spain, Switzerland, Turkey, the United Kingdom, Ukraine, COMESA, Israel, Mauritius and Mozambique, this edition features a chapter on Angola, which launched its Competition Regulatory Authority in early 2019.

In preparing this report, *Global Competition Review* has worked with leading competition lawyers and government officials. The latter group provides crucial perspective on the thinking behind cutting-edge matters such as the intersection of privacy, data and antitrust; 'phygital' retail distribution that combines brick-and-mortar with online sales; screening tools to detect collusion in public procurement; and much more.

The lawyers' and officials' knowledge and experience – and above all their ability to put law and policy into context – give the report special value. We are grateful to all of the contributors and their firms for their time and commitment to the publication.

Although every effort has been made to ensure that all the matters of concern to readers are covered, competition law is a complex and fast-changing field of practice, and therefore specific legal advice should always be sought. Subscribers to *Global Competition Review* will receive regular updates on any changes to relevant laws over the coming year.

If you have a suggestion for a topic to cover or would like to find out how to contribute, please contact insight@globalcompetitionreview.com.

Global Competition Review

London

June 2019

European Union: Pharmaceuticals

Jérémie Jourdan, James Killick, Assimakis Komninos, Strati Sakellariou-Witt and Axel Schulz¹ White & Case

This survey covers the main developments in the pharmaceutical sector in the European Union over the period 2018–2019.² The highlight of the past year has been rigorous judicial review of the decisions of the competition authorities in pharmaceutical cases, with patent settlements and excessive pricing remaining at the center of the attention. The most noticeable court developments include the General Court (GC) judgment in *Servier*, and the UK Competition Appeal Tribunal (the CAT) judgment in *Pfizer/Flynn*. Also, the UK Competition and Markets Authority's (CMA) scrutiny over rebate schemes in *Remicade* confirmed that the assessment of an alleged abuse of dominance should follow an effects-based approach. On the merger control front, the treatment of innovation in merger cases has continued to be an important topic. Finally, the European Commission (Commission) published its report on the enforcement of competition law in the pharmaceutical sector, while pharmaceutical sector inquiries are ongoing in France, Spain and Austria.

Patent settlement cases

Since its sector inquiry into the pharmaceutical sector closed 10 years ago, the Commission has continued to monitor settlements between pharmaceutical companies which are intended to resolve disputes on the validity or infringement 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 could in essence be 'pay-for-delay' agreements rather than good faith settlements of genuine legal disputes.

¹ 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.

² This article covers the period between May 2018 and April 2019.

The Commission's latest report on the monitoring of patent settlements was published on 9 March 2018 and covered the period from January to December 2016.³ It reaffirmed the Commission's commitment to subject B.II settlements⁴ to the highest degree of antitrust scrutiny,⁵ but fell 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, and settlements featuring minimal value transfers, at least until the EU courts provide definitive guidance as to the applicable test.

Some helpful guidance was provided by the EU judicature in the *Servier* and *Lundbeck* cases. The latter concern the two Commission decisions, taken in 2013 and 2014, where patent settlement agreements were found to restrict competition. In both cases, the addressees challenged the decisions before the EU courts. The GC presented a judgment in favour of the Commission in *Lundbeck* in September 2016, but the case is now under appeal before the Court of Justice of the European Union ('CJEU'). In *Servier*, several hearings took place before the GC in June and July 2017, and the judgment was delivered in December 2018, reducing the fines from \mathfrak{C} 331 million to \mathfrak{C} 228 million. Both Servier and the Commission appealed against the GC judgment in February 2019.

The Servier judgment covers both pharma market definition and whether patent settlements are a restriction of competition by object or by effect. The GC put the Commission decision under thorough scrutiny and reversed the latter's definition of the relevant market for perindopril, a molecule used to treat hypertension and heart failure. On the basis of expert evidence and medical studies, the GC identified a number of mistakes on the therapeutic substitution of perindopril with other ACE inhibitors, as well as on the doctors' choice not to prescribe different drugs for the same use. In addition, the GC emphasised that prices should not be the only or preponderant factor for the determination of the relevant product market in the pharma sector. The GC followed the CJEU in the AstraZeneca case¹² and noted that drugs are subject to competitive pressure on the basis of qualitative, non-price factors, such as the promotional efforts of drug makers, the patient's profile, the doctor's experience and the drugs' therapeutic differences. In light of these, the GC annulled the Commission's finding that the relevant market was limited to perindopril, and by consequence, annulled the finding of an abuse of dominance.

³ European Commission, Eighth report on the Monitoring of Patent Settlements, 9 March 2018.

⁴ 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.

⁵ Eighth report on the Monitoring of Patent Settlements, para. 17.

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 C-591/16 P, Lundbeck v Commission.

⁹ Case T-691/14, Servier and Others v Commission, EU:T:2018:922.

¹⁰ Case C-201/19 P, Servier and Others v Commission.

¹¹ Case C-176/19 P, Commission v Servier and Others.

¹² Case C-457/10 P, Astrazeneca v Commission.

As regards the disputed patent settlements, the GC held that four out of five, namely the ones concluded with Niche, Matrix, Teva and Lupin, constituted restrictions by object. For the GC, the relevant generics were potential competitors, and the settlements limited the generic drug makers' ability to challenge the validity of Servier's patents and commercialise their own products in exchange of a payment. In particular, the GC held that:

- generic drug makers are potential competitors to the patent owner, unless they rebut the Commission's findings by producing evidence of insurmountable technical, regulatory or financial barriers to entry;
- the presumption of validity of a patent does not lead per se to a presumption of infringement by the generic product, something that should be decided by the competent patent court;
- a settlement that includes non-challenge and non-commercialisation clauses, obtained in exchange of a 'reverse payment' higher than costs inherent to litigation constitute a restriction of competition by object.

The GC found that certain reverse payments would not lead to this conclusion, for example payments covering costs inherent to the litigation or payments of an amount insufficient to induce the generic to stay off the market.

Importantly, the GC also found that settlement agreements based on the strength of the litigious patent, and providing for a license on such patent on market terms, cannot be qualified as a restriction by object. The fifth patent settlement, between Servier and Krka, was held lawful, as the Commission failed to prove that the license was concluded on non-market conditions, and that the settlement had anticompetitive effects.

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 that 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'. Although proceedings were opened by the Commission in 2011, a Statement of Objections was only sent in July 2017, and a closed-door hearing took place in March 2018. The case is expected to be concluded in 2019.

Similarly, the CAT is examining an appeal by GSK and several generic companies against a decision of the CMA finding that GSK abused its dominant position and entered into anticompetitive agreements with generics manufacturers to delay their entry into the market. Noting that several of the issues raised by the case were subject to appeals before the EU courts in the *Lundbeck* and

¹³ 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.

Servier cases, the CAT decided to refer certain questions to the CJEU for a preliminary ruling. ¹⁴ The case is currently pending. ¹⁵ 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, or both.
- 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 as the latter was already examining Lundbeck's appeal and hearing the appeals in *Servier*. This means that the next two to three years are likely to be rich in jurisprudence, which will hopefully provide some much-needed clarification on these issues.

Excessive pricing in the pharmaceutical sector

Although 'unfair pricing' is listed as 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. Nonetheless, the last 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 ground-breaking 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. According to Aspen, a decision is expected in 2019. At the same time, national courts have developed the relevant case law during the course of 2018, with the CAT overturning the CMA's decision in *Pfizer/Flynn* and the Danish Competition Appeals Tribunal upholding the Danish Competition Council (DCC) decision in *CD Pharma*.

¹⁴ Generics UK Limited and ors. v Competition and Markets Authority [2018] CAT 4.

¹⁵ Case C-307/18, Generics (UK) and Others.

¹⁶ C-27/76, United Brands v Commission, ECLI:EU:C:1978:22.

¹⁷ 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).

Pfizer/Flynn

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. 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. On 7 June 2018 the CAT overturned the CMA's assessment on the existence of an abuse and sent the case back to the CMA. In parallel, in December 2018, the CMA was granted leave to appeal the CAT judgment. December 2018, the CMA was granted leave to appeal the CAT judgment.

The core of the CMA's finding that the prices charged by Pfizer and Flynn were excessive was that these 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. The CAT identified important errors in this legal test, and highlighted that a finding on abuse through excessive pricing should rely on 'proper evidence and analysis' and should respect the presumption of innocence. ²²

For the CAT, the CMA should not have relied on a theoretical and idealised cost plus methodology to determine excessiveness. On the contrary, it should have taken into account the 'real world'²³ and make comparisons with other products or companies. Referring to AG Wahl's Opinion in the recent *Latvian Societies* case, ²⁴ the CAT stated that a combination of methods should be used for setting a benchmark price and establishing the excess. ²⁵ In particular, an abuse can only 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. ²⁶

As regards unfairness, the CMA should have considered the prices of meaningful comparators, such as the phenytoin sodium tablets, suggested by Pfizer. The CAT criticised the CMA's assessment of the economic value, emphasising that this should have been made in light of all

¹⁸ CMA, Decision of 7 December 2016 in Case CE/9742-13, Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK.

¹⁹ 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.

²⁰ See https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products.

²¹ Pfizer Inc. and Pfizer Limited v Competition and Markets Authority; and Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority [2018] CAT 11 ('Pfizer/Flynn'), para. 5.

²² Ibid, paragraph 444.

²³ Ibid, paragraph 318.

²⁴ Opinion of AG Wahl, Case C-177/16, AKKA/LAA, EU:C:2017:286, paragraphs 36-45.

²⁵ Pfizer/Flynn, supra note 21, paragraphs 311-314.

²⁶ Opinion of AG Wahl, supra note 24, paragraphs 54, 112.

the relevant circumstances, including the patient benefits and the nature of the product.²⁷ Also, the CMA should have made sure that the alternative tests on unfairness would not lead to contradictory or self-excluding findings.²⁸

Other notable cases

The CMA has also opened investigations into Concordia and Actavis. In Concordia, the case was narrowed following the *Pfizer/Flynn* case, and a supplementary statement of objections was sent in January 2019. The investigation into Actavis was extended until June 2019 in anticipation of further evidence and analysis. 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,²⁹ increasing 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.³⁰

In Denmark, the Competition Appeals Tribunal upheld the DCC decision in *CD Pharma* in December 2018. 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. ³¹ 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.

Between 28 April and 27 October 2014, CD Pharma increased the price for Syntocinon by 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. As a result of the price increase, Amgros paid approximately six million kroner more than the original contract with Orifarm.

²⁷ Pfizer/Flynn, supra note 21, paragraphs 419, 425.

²⁸ ibid, paragraphs 428, 441.

²⁹ See the CMA press release of the CMA, available at https://www.gov.uk/government/news/ pharmaceutical-company-accused-of-overcharging-nhs.

³⁰ De-branded (genericised) drugs are not subject to price regulation in the UK.

³¹ 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'.

As in the *Pfizer/Flynn* and *Aspen* cases, the DCC based its analysis on the two limbs of the United Brands test. 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 DCC also compared the price charged in Denmark with its neighbouring countries.

Rebates in the pharmaceutical sector

On 14 March 2019, the CMA decided to close its investigation into the discount scheme for medicine Remicade by pharmaceutical company MSD, concluding that it was not likely to limit competition. In May 2017, the CMA had issued a statement of objections, alleging that MSD abused its dominant position by implementing a rebate scheme that impeded the sale of biosimilar versions of Remicade and dissuaded customers from switching to cheaper alternatives. In the concept of
The CMA's decision, in line with the CJEU in *Intel*,³⁵ found that rebates by undertakings in a dominant position are not *per se* illegal, and that a variety of factors need to be assessed for determining the existence of an abuse.³⁶ Focusing on the likelihood of the discount strategy to produce exclusionary effects, the CMA examined the rules applicable to the discount scheme and considered that it was designed with the intention of disincentivising the NHS to switch to biosimilar products. It also considered that, at the time when the scheme was launched, the NHS believed that it could lead to exclusionary effects.

However, the core of the CMA's analysis on the likelihood of exclusionary effects was the objective assessment of the circumstances of the market at the time of the introduction of the rebates in March and April 2015.³⁷ After conducting a thorough scrutiny that included surveying NHS staff, the CMA found that the NHS showed less clinical caution and a much greater willingness to use biosimilars instead of Remicade. Therefore, the market reality at the time MSD's discount scheme was introduced made any exclusionary effects unlikely.

Although the CMA justified its choice not to apply the as-efficient competitor test (AEC price/cost test) in the Statement of Objections,³⁸ the *Remicade* decision endorses the effects-based approach in unilateral conduct cases and confirms that competition authorities should carry out an economic analysis of the effects of discount schemes by dominant undertakings.

³² Case C-27/76, United Brands v Commission, EU:C:1978:22, paragraphs 250-252.

³³ See the CMA's statement at: https://www.gov.uk/government/news/cma-warns-businesses-after-ending-remicade-investigation.

³⁴ See https://www.gov.uk/cma-cases/pharmaceutical-sector-alleged-discounts-offered-on-a-product.

³⁵ C-413/14 P, Intel v Commission, EU:C:2017:632.

³⁶ CMA, No Grounds for Action Decision of 14 March 2019 in Case 50236, Remicade, p. 42.

³⁷ ibid, p. 63.

³⁸ Interestingly, in June 2016, the CMA closed an investigation into rebates applied to pharmaceuticals and confirmed that it will use the as-efficient competitor test, 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.

Mergers in the pharma sector

During the period covered in this report, the Commission reviewed eight transactions in the pharmaceutical sector. ³⁹ The transactions did not raise serious doubts as to their compatibility with the common market and led to simplified proceedings of clearance. ⁴⁰ The largest deal was the merger between Japanese Takeda and Irish Shire, which was approved subject to the divestment of a Shire pipeline drug, which would compete with a Takeda product. This reaffirmed the Commission's position in considering 'innovation' as an important parameter of competition. ⁴¹

Commission report on the competition enforcement in the pharmaceutical sector

On 28 January 2019, the Commission published its report on the enforcement of competition law in the pharmaceutical sector at EU and Member State level for the period 2009–2017.⁴² Since 2009, the authorities have together:

- adopted 29 antitrust decisions against pharmaceutical companies, imposing fines or making binding commitments to remedy anticompetitive conducts;
- investigated more than 100 other cases, while over 20 cases are currently pending; and
- reviewed more than 80 transactions.⁴³

The anticompetitive practices addressed in the 29 antitrust decisions referred mainly to cases of abuse of dominance, followed by different types of restrictive agreements which included 'pay-fordelay' agreements, bid rigging, and vertical agreements with distributors prohibiting them from representing products of competing manufacturers. ⁴⁴ The Commission highlighted that competition law enforcement contributes to delivering affordable medicines to patients and healthcare systems, while at the same time promotes innovation against practices that could have distorted the incentive to innovate.

³⁹ Commission decisions in Cases COMP/M.8889 - Teva/PGT OTC ASSETS, COMP/M.8955 - Takeda/Shire, COMP/M.9098 - Goldman Sachs/ORIX/ILS, COMP/M.9044 - CVC/Recordati, COMP/M.8974 - Procter & Gamble/Merck Consumer Health Business, COMP/M.8956 - Biogen/Samsung Biologics/Bioepis JV, COMP/M.8937 - Advent International/Zentiva, COMP/M.8916 - JIC/TAHL/Australia Nature's Care Biotech.

⁴⁰ See article 6(1)(b) of the EU Merger Regulation OJ L 24, 29.01.2004, p 1-22.

⁴¹ Similarly, the importance of 'innovation' was also emphasised by the Commission when, last year, it approved the pharma deal between Bayer and Monsanto, imposing on the companies obligations to divest entire lines of pipeline research. See 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).

⁴² Report from the Commission to the Council and the European Parliament, Competition enforcement in the pharmaceutical sector (2009-2017), COM(2019) 17 final, see: https://www.gsk.com/en-gb/media/press-releases/glaxosmithkline-plc-and-pfizer-inc-to-form-new-world-leading-consumer-healthcare-ioint-venture/.

⁴³ ibid, pp. 9, 14.

⁴⁴ ibid, p. 11.

National sector inquiries across Europe

During the last year, there were developments in the pharmaceutical sector inquiries across different member states.

In particular, the French Competition Authority started a new inquiry into the pharmaceutical industry in November 2017,⁴⁵ and launched a public consultation in October 2018.⁴⁶ The 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. It investigates biological medicines and focuses on two major subjects: (i) the pharmaceutical distribution chain; and (ii) medicine pricing.

The public consultation, completed in November 2018, addressed the interim assessment of the investigation as regards distribution in urban areas and chemical pathology, identifying (i) economic barriers to the adaptation of these sectors to the use of internet in the newly emerging delivery options; and (ii) the outdated nature of the current regulatory framework. ⁴⁷ A final opinion on these topics is expected soon, while a second opinion, on medicine pricing, is expected in summer 2019. ⁴⁸

The Spanish sector inquiry into the wholesale supply and marketing of medicines, which was launched on 17 March 2017,⁴⁹ is currently pending. In a preliminary finding, the Spanish Competition Authority (CNMC) had detected potential restrictions on competition arising from the functioning and structure of the Spanish market. The authority noted that the highly regulated sector needed to comply with the principles of necessity and proportionality to avoid introducing unjustified restrictions. The inquiry should analyse strategic behaviours of companies holding patents on innovative medicines that might restrict or delay the entry of generics. Moreover, the inquiry should 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.

In Austria, the Federal Competition Authority (AFCA) published in May 2018 its first interim report of the sector inquiry in the healthcare market.⁵⁰ The report analyses competition restrictions in the pharmacy market, focusing on the pharmacies' market entry and ownership structure, as well as on the general regulatory framework for pharmacies, including online sales and commercialisation of out-of-the-counter drugs. The AFCA also provided a list of recommendations addressing these issues from a competition law perspective.⁵¹

 $^{45 \}quad See \ http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=662\&id_article=3067\&lang=fr.$

⁴⁶ See http://www.autoritedelaconcurrence.fr/user/standard.php?lang=fr&id_rub=683&id_article=3283.

⁴⁷ See http://www.autoritedelaconcurrence.fr/doc/consultation_pub_sante_en.pdf.

⁴⁸ ibid.

⁴⁹ See:https://www.cnmc.es/sites/default/files/editor_contenidos/Notas%20de%20 prensa/2017/20170317_NP_Estudio_Medicamentos_eng.pdf

⁵⁰ See https://www.bwb.gv.at/en/news/detail/news/the_austrian_federal_competition_authority_publishes_ the_first_interim_report_on_the_austrian_pharm/.

⁵¹ See https://www.bwb.gv.at/fileadmin/user_upload/Veroeffentlichungen/The_Austrian_Pharmacy_Market_Recommendations_English.pdf.



Jérémie Jourdan White & Case

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 White & Case

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.



Assimakis Komninos White & Case

Assimakis (Makis) Komninos is a partner at the Brussels office of White & Case LLP. He is also a visiting fellow of the Centre for Law and Governance in Europe at University College London (UCL) and a member of the Executive Committee of the Global Competition Law Centre (GCLC) at the College of Europe. Makis has acted or been part of the defence team in a number of landmark cases before the European Courts, such as Microsoft (compulsory licensing), Google Shopping, Rambus (excessive pricing), GlaxoSmithKline (parallel trade of pharmaceuticals), Greek lignites (public undertakings) and Chalkor (human rights and antitrust) and has represented clients before the European Commission, other European competition authorities, courts and arbitration tribunals – including before the CAT in the recent Pfizer/Flynn excessive pricing case.

He has also been involved in complex Phase II merger clearance cases in the airline, energy and telecoms sectors. He is a prolific writer on competition law matters and is a non-governmental advisor to the International Competition Network (ICN). He is also a former Commissioner and Member of the Board of the Hellenic Competition Commission (HCC).



Strati Sakellariou-Witt White & Case

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.



Axel Schulz
White & Case

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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