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EUROPE, MIDDLE EAST AND AFRICA

ANTITRUST REVIEW 2021

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Preface

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

GCR's Europe, Middle East and Africa Antitrust Review 2021 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 region, this book provides an unparalleled annual update from competition enforcers and leading practitioners on key developments in both public enforcement and private litigation. In this edition, Sweden is a new jurisdiction alongside updates from the European Commission (including a new article on the abuse of dominance), Cyprus, Denmark, France, Germany, Greece, Norway, Portugal, Russia, Spain, Switzerland, Turkey, the United Kingdom, Ukraine, COMESA, Angola, Israel, Mauritius and Mozambique.

In preparing this report, Global Competition Review has worked with leading competition lawyers and government officials. Their 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 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 during 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.

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European Union: Pharmaceuticals

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White & Case

In summary

This article covers the main developments in the pharmaceutical sector in the European Union during the period 2018–2020.

Discussion points

- Antitrust in the pharmaceutical sector
- Patent settlement
- Excessive pricing
- Rebates
- Mergers in the pharmaceutical sector
- Pharmaceutical sector inquiries

Referenced in this article

- Austrian Federal Competition Authority
- UK Competition Appeal Tribunal
- Court of Justice of the European Union
- UK Competition and Markets Authority
- European Commission
- Danish Competition Council
- General Court
- Hellenic Competition Commission

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This survey covers the main developments in the pharmaceutical sector in the European Union between 2018 and 2020.[1] 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 centre of attention. The most noticeable court developments include the European Court of Justice's preliminary ruling in *Paroxetine*, and the UK Court of Appeal judgment in *Pfizer/Flynn*. Also, the UK Competition and Markets Authority's (CMA) scrutiny of 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 (the Commission) published its report on the enforcement of competition law in the pharmaceutical sector, while national competition authorities have been conducting their own pharmaceutical sector inquiries.

Patent settlement cases

Since its sector inquiry into the pharmaceutical sector closed 11 years ago, the Commission has continued to monitor settlements between pharmaceutical companies that 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.

The Commission's latest (and seemingly its last) report on the monitoring of patent settlements was published on 9 March 2018 and covered the period from January to December 2016.[2] It reaffirmed the Commission's commitment to subject B.II settlements[3] to the highest degree of antitrust scrutiny,[4] but fell short of providing guidance as to what is an acceptable settlement. In practice, to remain on the safe side, and avoid the risk of regulatory investigations, pharmaceutical companies should primarily consider early-entry types of settlements, and settlements featuring minimal or no-value transfers, even if the case law made it clear that the existence of a value transfer does not automatically tip a settlement into illegality.[5]

Some helpful guidance was provided by the EU judicature in the *Servier*, *Lundbeck* and *Paroxetine* cases.

Servier and *Lundbeck* concern two Commission decisions of 2013 and 2014 in which patent settlement agreements were found to restrict competition. In both cases, the addressees challenged the decisions before the EU courts. The General Court (GC) gave judgment in favour of the Commission in *Lundbeck* in September 2016,[6] but the case is now under appeal before the Court of

1 More specifically between January 2018 and April 2020, but with a focus on the past 12 months.

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', para. 17.

5 Case C-307/18, *Generics (UK) Ltd and Others v. CMA (Paroxetine)*, EU:C:2020:52.

6 Case T-472/13, *Lundbeck A/S and Lundbeck Ltd v. European Commission*, EU:T:2016:449.

Justice of the European Union (CJEU).[7] In *Servier*, the judgment was delivered in December 2018, reducing the fines from €331 million to €228 million.[8] Both Servier[9] and the Commission[10] 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 concluded that the Commission made several mistakes in its analysis of therapeutic substitution of perindopril with other ACE inhibitors[11] notably because it underestimated the competitive pressure exerted by other drugs that could be prescribed by doctors for the same therapeutic use. In addition, the GC emphasised that prices should not be the only, or even preponderant, factor for the determination of the relevant product market in the pharmaceuticals sector. The GC followed the CJEU in the *AstraZeneca* case[12] 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, which is the first time since the 1970s that a Commission decision under article 102 of the Treaty on the Functioning of the European Union (TFEU) in relation to a single dominant company was fully overturned on the merits. This judgment is important insofar as it confirms the need for a holistic analysis of price and non-price factors when defining the relevant markets.

As regards the disputed patent settlements, the GC held that four out of five, namely those 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 to 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; and
- 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.

7 Case C-591/16 P, *Lundbeck v. Commission*.

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

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

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

11 Angiotensin-converting-enzyme inhibitors are a class of medication used primarily for the treatment of high blood pressure and heart failure.

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

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 licence on that 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 licence was concluded on non-market conditions or that the settlement had anticompetitive effects.

The CJEU's judgment in *Paroxetine* arose in the context of the examination by the UK Competition Appeal Tribunal (CAT) of the appeal of 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. Following the oral hearing, the CAT decided to refer several questions to the CJEU for a preliminary ruling[13] to clarify the following issues:

- Potential competition – under which conditions an originator and a generic may be considered potential competitors?
- Restriction by object – may a patent settlement agreement be considered restriction by object?
- Restriction by effect – does the finding of a restriction by effect depend on the likelihood of generics having won the litigation or on the likelihood that a less restrictive agreement would have been entered into?
- Market definition – is competition from generic drugs prior to their effective entry to be taken into account when defining the market?
- Abuse of dominance – under which conditions can one or several patent settlement agreements constitute an abuse of a dominant position?

As regards potential competition, the Court confirmed classic case law, namely *Delimitis*,[14] and noted that the assessment of potential competition had to take into consideration the structure of the market, including the specificities of the pharmaceutical sector, the economic and legal context, and the facts of the particular case.[15] The Court underlined that if potential competition could not arise from the purely hypothetical possibility of such an entry, nor from the mere wish or desire of the generic manufacturer to enter the market, it should not either be required to demonstrate with certainty that the generic manufacturers would in fact enter.[16] Rather, the CJEU asserted that the appropriate approach was whether the generic manufacturer, notwithstanding the existence of the patent, had real and concrete possibilities of entering the market at the relevant time,[17] had the settlement agreement not been concluded.[18] The Court enumerated

13 *Generics (UK) Limited and Others v. Competition and Markets Authority* [2018] CAT 4.

14 Case C-234/89, *Delimitis v. Henninger Bräu*, EU:C:1991:91.

15 Case C-307/18, *op. cit.*

16 id., at para. 38.

17 id., at para. 50.

18 id., at para. 37.

the relevant factors that are to be taken into account in this assessment[19] and signalled that the existence of a transfer of value from the originator manufacturer to the generic manufacturer can indicate that there is a competitive relationship between these undertakings – the larger the transfer of value, the stronger the evidence that there is potential competition.[20]

Concerning the qualification of settlement agreements as restrictions 'by object', the Court recalled broad principles about the differences between restriction by object and by effect, confirming its modern case law (ie, *Cartes Bancaires* and *Maxima Latvija*)[21] and noted that the pro-competitive effects of an agreement could stop it from being a restriction by object where those effects gave rise to reasonable doubt as to whether the agreement caused a sufficient degree of harm to competition to constitute a restriction by object.[22] The CJEU also considered that an agreement to settle patent infringement proceedings should not automatically be considered a restriction by object simply because it involves a value transfer from the originator to the generic, as such a transfer could be justified if it is appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement. This would be the case, for instance, when the value transfer corresponded to costs incurred because of the litigation. However, the Court pointed out that a restriction will be characterised as 'by object' if the analysis of the agreement makes it clear that the transfers of value can only reflect the parties' commercial motivation not to engage in competition on the merits.[23]

Regarding the CAT's question on the notion of restriction by effect, the Court confirmed, according to *MasterCard*,[24] that a counterfactual analysis was necessary to determine the existence of restrictive effects. The Court noted that it was not necessary, for the purpose of conducting the counterfactual analysis, to determine precisely the chances of success of the generic manufacturer or originator manufacturer in the patent proceedings, or the probability of concluding a less restrictive agreement,[25] even if these factors could be taken into account, among others, to determine how the market would have operated and been structured in the absence of the agreement in question.[26]

On market definition, the question before the Court was narrow. Essentially, the Court was only asked to determine whether, in circumstances where an originator drug no longer had the protection of a molecule patent but benefited from a process patent of uncertain validity, generic versions of the drug should be included in the definition of the relevant market if they have not yet entered the market and it is not known if they can lawfully do so. In assessing the question, the CJEU noted the specificities of the pharmaceutical sector and the importance of the professional

19 id., at para. 51.

20 id., at para. 56.

21 Case C-67/13 P, *Groupement des Cartes Bancaires v. Commission*, EU:C:2014:2204 and Case C-345/14, *Maxima Latvija*, EU:C:2015;784.

22 Case C-307/18, *op. cit*., paras. 103 to 107.

23 id., at paras. 84 to 87.

24 Case C-382/12 P, *MasterCard and Others v. Commission*, EU:C:2014:2201.

25 id., at para. 119.

26 id., at paras. 115, 116, 117, 118 and 120.

circles' opinion, notably when considering interchangeability. The Court also remarked that generic manufacturers would have to be able to present themselves 'within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicine', that is notably the case when they have applied for market authorisation or have signed supply contracts with distributors.[27] Thus, the Court found that the existence of a process patent was not sufficient to prevent generic products from being considered as part of the relevant market, as a process patent (unlike a molecule patent) could not provide absolute certainty that a generic version of the originator's product could not enter the market.[28]

Finally, on the questions relating to the characterisation of an abuse of dominance, the CJEU found that when an overall strategy is capable of restricting competition and produces exclusionary effects that go beyond the specific anticompetitive effects of the individual agreements, this strategy can result in an abuse of dominant position.[29] The conclusions of the Court relied on the CAT's finding of the existence of a strategy that 'had, if not as its object, at least as its effect of delaying the market entry of generic medicines'.[30] Thus, the Court confirmed that the concept of abuse of a dominant position could encompass agreements that, although they did not individually breach article 101 of the TFEU, they did contribute to the cumulative anticompetitive effects of the other agreements.[31]

Owing to the narrowness of the CAT's questions, the CJEU's ruling in *Paroxetine* only offers limited insights on market definition and restrictions by effect. The Court is expected to give more guidance on these questions in its forthcoming *Servier* judgment.

There are also proceedings currently 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 United Kingdom and in the United States with a global agreement. Under the terms of the agreement, Teva agreed to keep its generic drug off the market in the European Economic Area 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'.[32] 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 2020.

27 id., at paras. 131 to 134.

28 id., at paras. 137 to 139.

29 id., at para. 172.

30 id., at para. 155.

31 id., at paras. 155 to 160.

32 See European Commission, press release, 'Commission sends Statement of Objections to Teva on "pay for delay" pharma agreement', 17 July 2017 (IP/17/2063).

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.[33] Nonetheless, in the past couple of years, excessive pricing cases in the pharmaceutical sector have been one of the hallmarks of EU competition enforcement. The national competition authorities have led the way and issued innovatory 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.[34] At the same time, national courts have recently developed the relevant case law, with the UK Court of Appeal upholding the CAT's decision to overturn the CMA's decision in *Pfizer/Flynn* and the Danish Maritime and Commercial Court upholding the judgment of the Danish Competition Appeals Tribunal confirming the Danish Competition Council (DCC) decision in *CD Pharma*.

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) for phenytoin sodium capsules.[35] This was the first decision of the CMA in a pure excessive pricing case and the highest fine imposed in the United Kingdom to date against a single company (*Pfizer*). Pfizer and Flynn brought the decision before the CAT on 7 February 2017.[36] 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.[37] On 10 March 2020, among other aspects, the Court of Appeal upheld the CAT's findings that the CMA (1) misapplied the relevant legal test for unfair pricing and (2) failed adequately to consider alternative, countervailing evidence adduced by Pfizer and Flynn.[38]

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. However, the CAT criticised the CMA for failing to evaluate properly the economic

33 Case C-27/76, *United Brands v. Commission*, EU:C:1978:22.

34 See European Commission press release, 'Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines', 15 May 2017 (IP/17/1323).

35 Competition and Markets Authority [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.

36 *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.

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

38 Cases C3/2018/1847 and 1874, *Competition and Markets Authority v. Flynn Pfizer and Pfizer Limited*, judgment of 10 March 2020, not yet reported.

value of phenytoin sodium capsules and wrongly relying on only one part of the *United Brands* test[39] ('price unfair in itself'), without properly assessing the prices of meaningful comparators. The CAT also held that the CMA gave too little consideration of the evidence adduced by Pfizer and Flynn regarding the prices of comparator drugs and quashed the CMA's finding of abuse, but remitted the case back to the CMA for further consideration in light of the judgment. Much of the debate before the Court of Appeal concerned the unfairness limb, particularly the need to consider comparator prices if a competition authority has determined that the price is unfair 'in itself'.

The Court of Appeal noted that the two-limb *United Brands* test for unfairness was not to be followed slavishly and was neither a purely disjunctive (ie, one or the other) nor a combinatorial test, thus confirming the CAT's finding that the 'in itself' and 'by comparison' options under the second limb of *United Brands* were not strict alternatives. The Court held that although a competition authority is free to choose whatever means it sees fit to show unfair pricing (whether 'in itself', by comparison, or otherwise), it must have due regard for alternative, exculpatory evidence put forward by the firm being investigated. The Court of Appeal reached this finding relying on the approach taken by the CJEU in its seminal *Intel* ruling.[40] Lord Justice Green held that *Intel* 'makes clear that if an undertaking adduces evidence of a type unlike that which the competition authority relies upon to establish an abuse then the authority is under a duty to consider that evidence'.[41]

The case has been referred back to the CMA, which can assess Pfizer/Flynn's pricing of phenytoin sodium capsules *de novo*. In light of the Court of Appeal's judgment, that must include taking due account of Pfizer and Flynn's countervailing evidence, notably on the price of a comparator drug, phenytoin sodium tablets.

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. Regarding *Actavis*, the CMA has been conducting three separate investigations concerning excessive and unfair pricing, anticompetitive agreements and abusive conduct. In March 2017, 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 United Kingdom,[42] increasing the price of the 10mg tablets by more than 12,000 per cent and of the 20mg tablets by nearly 9,500 per cent, compared to the branded version of the drug.[43] In February 2020, taking into

39 The Court of Justice held in *United Brands* that a price can be unlawfully excessive if it bears 'no reasonable relation to the economic value of the product supplied', with that question being determined (among other possible methods) according to the following test: (1) whether the difference between the costs incurred and the price charged is excessive (the 'excessiveness limb') and, if so, (2) whether the price was unfair either (a) in itself or (b) when compared to the price of competing products (the 'unfairness limb').

40 Case C-413/14 P, *Intel Corporation Inc. v. Commission*, EU:C:2017:632.

41 Cases C3/2018/1847 and 1874, *op. cit*. Judgment of Green LJ at para. 89.

42 CMA press release, 'Pharmaceutical company accused of overcharging NHS', (16 December 2016), at https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs.

43 Debranded (genericised) drugs are not subject to price regulation in the UK.

account the interrelationship of the facts and allegations, the CMA decided to bring together the three investigations it had been conducting until then and issued a supplementary statement of objections to Actavis.[44]

In Denmark, the Maritime and Commercial Court upheld the judgment of the Danish Competition Appeals Tribunal in March 2020,[45] thus confirming the DCC decision in *CD Pharma* (December 2018). On 31 January 2018, the DCC found that the pharmaceutical distributor CD Pharma had abused its dominant position by charging unfair prices.[46] 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 on 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 6 million kroner more than the original contract with Orifarm.

As in the *Pfizer/Flynn* and *Aspen* cases, the DCC based its analysis on the two limbs of the *United Brands* test.[47] 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 'of itself' and compared to competing products. The DCC also compared the price charged in Denmark with its neighbouring countries.

Earlier, in July 2018, the Hellenic Competition Commission (HCC) published its long-awaited decision in the post-*Lelos* saga involving parallel trade.[48] This was the latest and probably last episode in a series of cases that marked the 2000s with two preliminary rulings by the CJEU[49] and a number of decisions in Greece. The case is historical, since the facts happened almost 20 years

44 CMA press release, 'Hydrocortisone tablets: alleged excessive and unfair pricing, anti-competitive agreements and abusive conduct (50277)' (12 February 2020), at https://www.gov.uk/cma-cases/hydrocortisone-tablets-alleged-excessive-and-unfair-pricing-anti-competitive-agreements-and-abusive-conduct-50277.

45 Danish Competition Council press release, 'Sø- og Handelsretten: CD Pharma satte en ulovlig høj pris' (3 March 2020), at https://www.kfst.dk/pressemeddelelser/kfst/2020/20200302-cd-pharma-sh/ (in Danish).

46 Decision of the Danish Competition Council of 31 January 2018, 'CD Pharmas prissætning af Syntocinon'. See also Danish Competition and Consumer Authority press release, 'CD Pharma has abused its dominant position by increasing their price by 2,000 percent' (31 January 2018).

47 Case C-27/76, *United Brands v. Commission*, EU:C:1978:22, paras. 250 to 252.

48 See HCC Decision 605/2015.

49 See Case C-53/03, *Synetairismos Farmakopoion Aitolias and Akarnanias (Syfait) and Others v. GlaxoSmithKline plc and GlaxoSmithKline AEVE*, EU:C:2005:333; Joined Cases C-468/06 to C-478/06, *Sot. Lelos and Others v. GlaxoSmithKline AEBE*, EU:C:2008:504.

ago. This was about GSK implementing certain emergency measures in Greece curbing sales to parallel exporters for three prescription medicines that were very much in demand for export. These medicines were singled out by exporters because the Greek state had fixed prices at a low level in comparison to countries such as Germany and the United Kingdom, where prices were fixed at a higher level. The enormous arbitrage opportunities had led to severe shortages in Greece. To a large extent, the HCC was reviewing GSK's conduct *de novo* after an earlier HCC decision (that was positive to GSK) was annulled by the Athens Administrative Court of Appeal (the wholesalers were successful in their appeals).

The case is interesting because the HCC was implementing for the first time the criteria set by the CJEU in *Lelos*. In so doing, the HCC made a fundamental distinction in its evaluation of GSK's conduct that depended on whether a pharmaceutical company refuses to supply 'predominantly exporting wholesalers' or other wholesalers that focus on the local market even if they may also engage in some exports. In the former case, GSK's conduct was justified and to that extent the HCC rejected formally the complaints coming from the exporting wholesalers. On the other hand, the HCC accepted the complaints by some of the other wholesalers for two of the three medicines that were at stake and imposed a fine on GSK.

Rebates in the pharmaceutical sector

On 14 March 2019, the CMA decided to close its investigation into the discount scheme for the medicine Remicade by pharmaceutical company MSD, concluding that it was not likely to limit competition.[50] 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.[51]

The CMA's decision, in line with the CJEU in *Intel*,[52] 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.[53] 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 UK National Health Service (NHS) to switch to biosimilar products. It also considered that, at the time 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.[54] After conducting a thorough scrutiny that included surveying NHS staff,

50 See the CMA's statement at https://www.gov.uk/cma-cases/pharmaceutical-sector-alleged-discounts-offered-on-a-product, or refer to the CMA decision (see footnote 53, below).

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

52 Case C-413/14 P, *Intel v. Commission*, EU:C:2017:632.

53 CMA, No Grounds for Action Decision of 14 March 2019 in Case 50236, *Remicade*, p. 42, at https://assets.publishing.service.gov.uk/media/5c8a353bed915d5c071e1588/Remicade_No_Grounds_For_Action_decision_PDF_A.pdf.

54 id., at p. 63.

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 (price against cost) in the statement of objections,[55] 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.

Mergers in the pharmaceutical sector

During the period covered in this report, the Commission reviewed 14 transactions in the pharmaceutical sector.[56] Most of them did not raise serious doubts as to their compatibility with the common market and led to simplified proceedings of clearance.[57] However, four mergers were cleared subject to conditions. One 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.[58]

A second merger related to the acquisition of Pfizer's Consumer Health Business by GlaxoSmithKline and was conditional upon the global divestment of Pfizer's topical pain management business carried out under the ThermaCare brand.[59]

55 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.

56 Commission decisions in Cases COMP/M.9274 – *Glaxosmithkline/ Pfizer Consumer Healthcare Business*, COMP/M.9461 – *Abbvie/Allergan*, COMP/M.9547 – *Johnson & Johnson/Tachosil*, COMP/M.9610 – *CVC/Royal Frieslandcampina/DMV Fonterra Excipients*, COMP/M.9540 – *Permira/Cambrex*, COMP/M.9294 – *BMS/Celgen*, 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*.

57 See article 6(1)(b) of the EU Merger Regulation OJ L 24, 29.01.2004, pp. 1 to 22.

58 Similarly, the importance of 'innovation' was also emphasised by the Commission when, in 2019, 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 also European Commission press release, 'Commission clears Bayer's acquisition of Monsanto, subject to conditions', 21 March 2018 (IP/18/2282).

59 Commission Decision in Case COMP/9274, *Glaxosmithkline/Pfizer Consumer Healthcare Business*.

The third was the acquisition of GE's BioPharma business by Danaher.[60] The Commission approved the operation subject to the sale of five Danaher businesses to a purchaser with experience in the supply of biotech equipment or consumables in Europe, Middle East and Africa, the Americas and Asia,[61] approved in March 2020.

Finally, the fourth case related to the acquisition of Allergan by AbbVie and was approved by the Commission subject to the divestment of a product Allergan was developing to treat inflammatory bowel diseases.[62]

Commission report on competition enforcement in 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.[63] During this period, 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 at least 20 cases are currently pending; and
- reviewed more than 80 transactions.[64]

The anticompetitive practices addressed in the 29 antitrust decisions referred mainly to cases of abuse of dominance, followed by different types of restrictive agreements that included 'pay-for-delay' agreements, bid rigging and vertical agreements with distributors prohibiting them from representing products of competing manufacturers.[65] 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.

National sector inquiries across Europe and other developments

During the last few years, there have been developments in pharmaceutical sector inquiries in different member states.

In particular, the French competition authority handed down its opinion concerning the pharmaceutical distribution of drugs in urban areas and chemical pathology in April 2019.[66] The inquiry followed a previous sector inquiry, published in 2013, and aimed at assessing whether

60 Commission Decision in Case COMP/M.9331, *Danaher/GE Healthcare Life Sciences Biopharma*.

61 See European Commission press release, at https://ec.europa.eu/commission/presscorner/detail/en/IP_19_6809.

62 Commission Decision in Case COMP/M.9461, *AbbVie/Allergan*.

63 Report from the Commission to the Council and the European Parliament, 'Competition enforcement in the pharmaceutical sector (2009-2017)', COM(2019) 17 final, at https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf.

64 id., at pp. 9 and 14.

65 id., at p. 11.

66 French Competition Authority, Opinion 19-A-08 of 4 April 2019.

the recommendations of the authority have been followed and how the French pharmaceutical sector has evolved in recent years. In its report, the French competition authority made concrete proposals for an evolution of regulatory framework concerning (1) online selling, (2) advertising and (3) the possibility to open the capital of pharmacies. The French authority also made a suggestion to reduce the scope of the French monopoly on dispensing medicinal products, in favour of alternative distribution methods.

In Austria, the Federal Competition Authority (AFCA) published two interim reports of the sector inquiry into the healthcare market in May 2018[67] and October 2019.[68] The first 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 over-the-counter drugs. The AFCA also provided a list of recommendations addressing these issues from a competition law perspective.[69] The second report analyses the market for healthcare in rural areas and addresses the following topics:

- the inventory of regional supply with pharmacies and general practitioners;
- medical shortages and health policy measures;
- medical pharmacies;
- primary care units, employment of doctors and teaching practice; and
- proposals from the Austrian Chamber of Pharmacists for the modernisation of the Pharmacies Act.

Additional reports are expected in the medical sector.[70]

67 Austrian Federal Competition Authority, Part I of the Sector Inquiry Health report, 'The Austrian Pharmacy Market', 18 May 2018.

68 Austrian Federal Competition Authority, Part II of the Sector Inquiry Health report, 'Healthcare in Rural Areas', 16 October 2019.

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

70 See https://www.bwb.gv.at/news/detail/news/branchenuntersuchung_gesundheit_bwb_veroeffentlicht_zwei_teilberichte/.

Jérémie Jourdan
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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 of Justice in the largest case to date concerning patent settlement agreements. The case involves the application of both articles 101 and 102 of the Treaty on the Functioning of the European Union.

James Killick
White & Case

James Killick led the firm's global pharmaceuticals and healthcare practice from 2010 to 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.

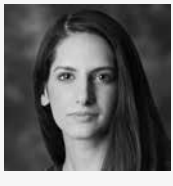
He has been involved in pleading a number of leading cases in the European Courts, including *Microsoft v. Commission* (compulsory licensing; treatment of trade secrets), *Hanner* (Swedish retail monopoly on pharmaceuticals), *Pfizer v. Council* (precautionary principle), *IMS Health* (compulsory licensing), 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 and a member of the Executive Committee of the Global Competition Law Centre 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* (self-preferencing), *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. He also acted 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 adviser to the International Competition Network. He is also a former commissioner and member of the board of the Hellenic Competition Commission.



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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, advising 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
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Axel Schulz advises on a broad range of European Commission 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 its 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 favourable judgments for Abbott in two Greek court cases initiated by Greek pharmaceutical wholesalers requesting large quantities of prescription medicines so as to export them. He has also represented GlaxoSmithKline in a number of cases before the European courts in Luxembourg.

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