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Dominance in the pharmaceutical sector: An overview of EU and national case law

DOMINANCE (ABUSE), DOMINANCE (NOTION), COLLECTIVE DOMINANCE, EXCESSIVE PRICES, INTELLECTUAL PROPERTY, PHARMACEUTICAL, FOREWORD, JUDICIAL REVIEW, MARKET DEFINITION, THRESHOLDS, MERGER (NOTION), PAY-FOR-DELAY

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In a communication of November 2020, the European Commission (the "**Commission**") presented its 'new Pharmaceutical Strategy for Europe' [*1*], the main objective of which is to achieve a strong, fair, competitive, and green pharmaceutical industry, centered on patients' needs. The Commission's ambition is to remove existing barriers that prevent patients' access to innovative and affordable medicines, while facilitating the digital transformation of the industry. In this context, the enforcement of competition rules certainly remains an important instrument for the Commission to achieve its goals and we expect the sector to remain a key priority throughout the European Union ("**EU**"). Just in the past year, several important decisions have been adopted and multiple investigations opened, both in antitrust and merger control.

Regarding merger control, the Commission announced in March 2021 the creation, at the initiative of the United States Federal Trade Commission, of a multilateral working group to review the effects of mergers and align enforcement policies in the pharmaceutical sector [*2*]. The working group is expected to address concerns amongst regulators regarding the increased number of transactions and concentration of the market on both sides of the Atlantic. In this context, the objective of the group, as presented by the Commission, is to identify "*concrete and actionable steps*" to capture potentially problematic pharmaceutical mergers and reinforce their analysis in the future. However, to the best of our knowledge, this group, in which the Commission and the FTC have been joined by the U.S Department of Justice, the Canadian Competition Bureau and the UK's Competition and Markets Authority ("**CMA**"), has so far not been very active. It thus remains to be seen what will actually come out of this initiative.

In the meantime, the Commission's renewed interpretation of Article 22 of the EU Merger Regulation, allowing it to review transactions that normally fall below European and even national thresholds, should already bring some important changes in EU merger control. The Commission has indicated, in its guidance issued on 26 March 2021 [*3*], that, through the referral mechanism set out in Article 22 of the EU Merger Regulation, it intends

to capture pharmaceutical mergers where the turnover of at least one undertaking involved does not reflect its actual or future competitive potential. The first transaction that has been referred to the Commission on that basis is the USD 7.1 billion *Illumina / Grail* merger, which led to the opening of a phase II investigation in July 2021 [*4*]. In parallel, the referral of the merger is being challenged before the General Court of the EU, on the ground that the Commission does not have jurisdiction to review it [*5*]. The analysis of the parties in that respect likely contributed to Illumina's decision to finalize its acquisition of Grail without waiting for the green light of the Commission, originally expected for November 2021 at the latest. The latter immediately reacted by launching an investigation against the parties for gun jumping in August 2021 [*6*], rapidly followed, in October 2021, by the imposition of interim measures [*7*] to prevent potential negative effects on competition while the review of the *Illumina / Grail* merger is still pending [*8*].

On the antitrust front, this past year has also brought some interesting developments, both at the EU and national level.

Despite not being a dominance case, the confirmation of the *Lundbeck* judgment by the European Court of Justice ("**ECJ**") is one of the major decisions of 2021 [*9*]. By way of background, Lundbeck and several generic manufacturers of the active substance citalopram were fined in 2013 by the Commission for patent settlements involving significant reverse payments from Lundbeck to its competitors aimed at delaying generic entry on the market (so-called "pay-for-delay" agreements). In its judgments of 25 March 2021, the ECJ dismissed all appeals. Along the lines of the *Generics UK* preliminary ruling [*10*], the ECJ confirmed that such pay-for-delay agreements may amount to a restriction of competition "by object" when it is plain that the transfer of value at stake has no explanation other than the parties' common commercial interest not to engage in competition on the merits. A case-by-case analysis is however necessary to make that determination.

Beyond this important confirmation, the ECJ also clarified the conditions under which a generic company can be considered a potential competitor of the originator on the relevant market. In that respect, the ECJ indicated that, in the context of a market recently opened to competition as a result of the originator's loss of exclusivity, a generic manufacturer may be deemed a potential competitor if there is evidence that it has the firm intention and inherent ability to penetrate the market and does not face insurmountable barriers to entry.

The question of the market definition in the pharmaceutical sector will also soon be revisited, either generally, as the Commission is currently reviewing its market definition notice, or more specifically in the context of the new questions referred to the ECJ by the Italian Council of State in the Italian branch of the *Avastin / Lucentis* case. In that case, the possibility to include in the relevant market drugs that are used off-label will again be debated (**I.**).

Another noteworthy area of development in 2021 was the scrutiny of lifecycle management strategies allegedly implemented by pharmaceutical companies to protect their drugs from competition. In this respect, alongside traditional strategies (such as those based on prices), pharmaceutical firms are becoming more and more creative. As a result, the attention of the authorities has started to slowly shift towards new types of conduct, with notably growing concerns around the use of IP rights to delay competition and the implementation of communication strategies targeting competing drugs (**II.**). In an October 2021 speech, Margrethe Vestager, European Vice President and Commissioner in charge of competition, stated that "*drug companies are using new ways to fight off the threat that competition will eat away at their profits, misusing the courts and the patent system to keep generics out, or buying up smaller rivals that are developing competing drugs, only to further stifle competition*" [*11*]. Similarly, the French Competition Authority's novel theory of harm in the *Avastin / Lucentis* case, focusing on the off-label use of a medicine, and the investigation opened by the Commission

earlier this year against Teva for an alleged misuse of the patent system and implementation of a disparagement campaign against generics, are good examples of the new areas of risks for pharmaceutical companies.

Finally, the last but still very important area of concern for the pharmaceutical industry remains excessive pricing, where enforcement activity is continuing at a rapid pace (**III.**). The Commission has issued its long-awaited decision in the *Aspen* case and some of the NCAs investigating Lediant have reached the conclusion that the latter breached competition rules and started to impose fines against the company. While the UK is no longer part of the EU, the CMA remains very active on this front and its decisions, insofar as they rely on EU case law, continue to provide useful guidance for companies.

I. Market definition in the pharmaceutical sector

The definition of the relevant market is a pre-requisite to establishing a dominant position. As such, it plays a critical role in the analysis by the Commission and NCAs of a potential infringement of Article 102 of the Treaty on the Functioning of the European Union ("**TFEU**") and in the defense strategy of pharmaceutical firms accused of abusive conduct.

Traditionally, the Commission and NCAs have relied on level 3 of the Anatomical Therapeutical Chemical ("**ATC**") classification as a starting point to define relevant markets. Level 3 of the ATC groups medicines based on their therapeutic indications. However, in abuse of dominance cases involving originator and generic companies, the tendency has always been to define the market more narrowly, at the level of the molecule, which leaves only little room for debate regarding the dominant position of the originator company.

While challenges to this strict approach have generally been unsuccessful, the General Court's judgment in the *Servier* case [***12***] has brought hope. The General Court did not deny that generic drugs, which are placed on the market at a lower price than their reference medicines, exert a strong competitive constraint on the price and sales of the latter, justifying that originator drugs and their generics be considered as belonging to the same relevant market. Yet, the General Court also recalled that the definition of the relevant market in the pharmaceutical sector must take due account of "*another essential factor in the analysis of competitive interactions, specific to that sector*" [***13***], which is the choice of treatment by prescribing doctors. In practice, such choice is not determined by the cost of medicines but, to the contrary, primarily by the marketing authorization and prescribers' perception of the effectiveness and appropriateness of a given medicine to treat their patients' conditions. As underlined by the General Court, this specific feature of the pharmaceutical sector permits "*the operation of significant qualitative and non-price competitive constraints in addition to the usual mechanisms of price pressure*" [***14***], which affect the definition of relevant markets.

In this case, this led the General Court to overturn the Commission's initial finding that Servier was in a dominant position on the market for perindopril (a blood pressure control medicine that was Servier's best-selling drug). A thorough analysis of prescribers' habits and scientific data indeed showed that perindopril did not significantly differ, in terms of therapeutic use, from other ACE inhibitors (i.e. drugs that help relax the veins and arteries to lower blood pressure). When including the latter in the relevant market, instead of only Servier's drug and the generics, Servier was no longer in a dominant position. The Commission has appealed the General Court's judgment on this specific aspect to the ECJ, whose ruling is now expected in the course of 2022 [***15***].

The definition of relevant markets in the pharmaceutical sector has recently raised two other important issues, regarding whether it is appropriate to include in the relevant market drugs that are either (1) unlawfully placed on the market (in breach of a presumably valid patent, which normally confers a monopoly to its holder) or (2) used outside the scope of their marketing authorization.

The ECJ provided guidance on the first issue in its preliminary ruling of 30 January 2020 [***16***] (*UK Paroxetine* case). In this case, GSK challenged the fact that generics looking to enter the market could be included in the relevant market as its originator drug was still protected by a presumably valid manufacturing process patent, thus making any entry on the market necessarily illegal. However, according to the ECJ, to determine whether there is a sufficient degree of interchangeability between the originator drug and a generic version of such drug which is not yet on the market, it must be ascertained whether generic manufacturers have the ability to enter the market within a relatively short timeframe so as to constitute "*a serious counterbalance*" to the manufacturer of the originator drug already on the market. In this respect, the fact that the originator company holds a process patent covering the manufacturing of its drug is not in itself decisive to exclude generic versions from the relevant market. Despite the high level of protection of intellectual property rights in the EU, the originator manufacturer has no guarantee that a generic version containing the same active ingredient, which is in the public domain, may not be lawfully placed on the market, using another manufacturing process, or that the validity of the manufacturing process patent may not be successfully challenged.

Following this ruling, the UK Competition Appeal Tribunal ("**CAT**") confirmed earlier this year that originator and generic versions of paroxetine were part of the same market at the time of the challenged agreements between GSK and generic companies. The CAT found that generic manufacturers, although not yet on the market, already exercised a competitive constraint on GSK and, without GSK's intervention to delay their entry, would have been able to penetrate the market in a relatively short period of time [***17***].

The second issue, regarding the substitutability between a medicine having a marketing authorization for a certain indication and another medicine used off-label for the same purpose, was addressed by the ECJ in its preliminary ruling of 23 January 2018 in the *Avastin / Lucentis* case, following a referral from the Italian Council of State [***18***]. In its judgment, the ECJ allowed for the possibility that Avastin, used off-label to treat wet AMD (an eye disease), could be regarded as being in the same market as Lucentis, authorized in this indication, provided that there exists "*a sufficient degree of interchangeability*" between the two drugs. The ECJ however held that this interchangeability cannot be determined without competent authorities or courts having pre-determined that such off-label use complies with national provisions concerning the manufacturing or marketing of the product.

In Italy, where the *Avastin / Lucentis* case has been dealt with under Article 101 TFEU, the Council of State initially dismissed, in a judgment of 15 July 2019, the appeals brought by Roche and Novartis. The Council of State confirmed the fines imposed on the latter for having breached competition law, totaling approximately 180 million euros. But Roche and Novartis subsequently brought a further action before the Council of State asking for revision of its judgment because it failed to take due account, in the definition of the relevant market, that Italian authorities considered Avastin's off-label use to be illegal. In June 2021, the Council of State referred to the ECJ new questions for a preliminary ruling, including one concerning the consequences for market definition purposes of the determination by the Italian authorities regarding the unlawfulness of Avastin's off-label use [***19***]. The ECJ's answer is all the more expected because, in parallel criminal proceedings against legal representatives of Roche and Novartis for stock manipulation, the Tribunal of Rome, and then the Court of Rome, both found that the two drugs did not compete in the market.

In France, where the case is currently pending before the Paris Court of Appeal, the FCA took a very different approach [*20*]. It chose to address the case under Article 102 TFEU and Article L. 420-2 of the French Commercial Code claiming an abuse of collective dominance by Roche and Novartis on the French market for the treatment of wet AMD. To reach that conclusion, the FCA included Avastin in the relevant market despite the regulatory constraints surrounding the compounding of Avastin and preventing, throughout the infringement period, its prescription off-label in presence of an authorized drug on the market. According to the FCA's theory, Avastin and Lucentis compete on the market for the treatment of wet AMD because (i) Novartis identified Avastin as being a threat for Lucentis, (ii) some doctors continued to prescribe it off-label after Lucentis obtained its marketing authorization, and (iii) based on the FCA's own interpretation of contemporaneous scientific studies, the two drugs would have the same efficacy and offer a comparable level of security for patients. As the FCA, contrary to its Italian counterpart, chose to address the case under Article 102 TFEU and Article L. 420-2 of the French Commercial Code, the definition of the relevant market is obviously a central question that the Court of Appeal will have to resolve before considering whether the conducts at stake can be deemed abusive under competition law.

Finally, it is worth noting that the Commission is currently in the process of revising its notice on market definition, which was adopted in 1997. In its Staff Working Document of 12 July 2021 [*21*], summarizing the findings of the evaluation of the notice, the Commission noted that, while the notice remains relevant, it needs to be adapted to modern times. Over the past twenty years, demand and supply characteristics have drastically changed as the economy has become increasingly digital, global and interconnected. Against this background, the Commission has identified several areas where the content of the notice would benefit from being enriched, including new developments on non-price parameters of competition, such as innovation, which obviously plays a significant role in the pharmaceutical industry.

II. Misuse of IP rights and communication strategies: the new hazardous area for pharmaceutical firms

Following the results of its sector enquiry in 2009, much of the Commission's efforts were devoted to tackling so-called pay-for-delay agreements, with no less than four investigations launched and fines totaling more than 500 million euros imposed in the last eight years against various originator and generic pharmaceutical compagnies (the latest one amounting to 60.5 million euros in the *Teva / Cephalon* case [*22*]). However, recent developments suggest that the Commission may now focus its attention on other types of conduct that had so far attracted only limited scrutiny.

The formal investigation opened by the Commission against Teva in March 2021 for alleged misuse of its IP rights and implementation of a disparagement strategy against generic versions of its blockbuster drug Copaxone®, used for the treatment of multiple sclerosis [*23*], is a good illustration of this perceived new trend. In this case, the Commission will first have to determine whether Teva has artificially extended its market exclusivity for Copaxone and delayed generic entry through an alleged strategy of repeated filings and withdrawals of divisional patents that forced generic companies to file new legal challenges each time. It will also for the first time examine whether Teva's communication campaign, primarily directed at healthcare institutions and professionals, insisting on the risks associated with the use of generic versions of Copaxone, ought to be qualified as an abuse of dominant position under Article 102 TFEU.

The position taken by the Commission in this case will have consequences for the future conduct of pharmaceutical companies. Yet, one should not forget that guidance – although still relatively isolated – already exists on so-called misuse of IP rights and disparagement strategies, mostly at the national level but also, to

some extent, in EU case law.

First, the alleged misuse by Teva of its IP rights echoes the Italian *Pfizer* case, where the latter was found to have abused its dominant position based on similar conduct, enabling it to artificially prolong the market exclusivity for its drug Xalatan. In a judgment of 2014 [*24*], the Italian Council of State confirmed the Italian Competition Authority's preliminary view that Pfizer had unduly exploited the patent system by filing for a divisional patent, an Italian supplementary certificate of protection, and a pediatric extension, with the objective to delay generic entry. According to the Italian highest court, these practices went beyond mere patent protection and formed part of a wider legal strategy to hinder competition, which also included sending warning letters to generic companies, filing legal proceedings against competitors, and taking actions targeting the AIFA (the Italian Medicines Authority) to dissuade it from including generic versions of Xalatan on the transparency list.

At the EU level, the landmark *AstraZeneca* case will also certainly serve as a benchmark in the Commission's analysis of Teva's behavior. In 2005, AstraZeneca was sanctioned with a 60 million euros fine for misusing the patent system to delay generic entry. At the time, the Commission, whose decision was later upheld by European courts [*25*], found that AstraZeneca purposely gave misleading information to several national patent offices in Europe to gain extended patent protection of its blockbuster drug Losec through so-called supplementary protection certificates.

Second, although the Commission and European courts have considered that improper communications, in the form of misleading messages conveyed to the public, healthcare professionals or health authorities, may trigger antitrust liability [*26*], it will be the first time that the Commission will examine more thoroughly an alleged disparagement campaign against generics. This type of practice has, however, been the subject of close scrutiny by other competition authorities in the EU, notably by the FCA which has a long track record of enforcement against pharmaceutical companies engaged in disparagement of competing drugs.

In a landmark 2013 decision, the FCA sanctioned Sanofi 40.6 million euros for implementing a global communication strategy targeted at healthcare professionals for purposes of delaying the entry of generic versions of Plavix on the French market. [*27*] Although Sanofi's communication was based on accurate facts, it was found to have abused its dominant position by presenting information about the properties of its drug Plavix and that of generic versions in a misleading way. According to the FCA, Sanofi's communication was designed to take advantage of the general risk aversion of health professionals and instill doubt in their minds as to the bioequivalence between the two, even though the generic versions had already obtained their marketing authorization.

More recently, in the *Durogesic* case, the FCA fined Janssen-Cilag (a subsidiary of the Johnson & Johnson group) 25 million euros for having abused its dominant position through the adoption of a global communication strategy targeted at healthcare professionals and health authorities, with the alleged objective to delay generic entry on the French market of its blockbuster drug Durogesic, an opioid containing the active ingredient fentanyl used for pain relief [*28*].

The novelty of this case was the characterization as an abuse of dominance of Janssen Cilag's repeated and allegedly unlawful intervention before the ANSM (the French Medicines Agency). More particularly, the FCA considered that Ratiopharm's entry was delayed in France as a consequence of Janssen Cilag's behavior, which allegedly relied on alarmist and scientifically unfounded arguments to challenge the bioequivalence of generics, even though bioequivalence had already been expressly recognized by the Commission, thereby leaving no

choice to the ANSM but to grant a marketing authorization to Ratiopharm's specialty. On appeal [*29*], Janssen Cilag's fine was slightly reduced because the Paris Court of Appeal recognized that Janssen Cilag's conduct was not intended to prevent the granting of a marketing authorization for Ratiopharm but merely to challenge the inclusion of its generic on the so-called generic list. That inclusion would have allowed for automatic substitution by pharmacists between Durogesic and its generic version whereas, according to Janssen-Cilag, such automatic substitution could entail risks for patients stabilized under Durogesic.

Last, but not least, the FCA recently imposed a record fine of 444 million euros on Roche and Novartis for an alleged abuse of collective dominance in the French market for the treatment of wet AMD, an ophthalmic condition affecting mainly the elderly [*30*]. However, by contrast with the distinction made in the*Durogesic* case, where the Paris Court of Appeal had explained that the FCA does not have jurisdiction to review and analyze the validity of scientific arguments presented to health authorities, the FCA went one step further in the assessment of communications of pharmaceutical companies with the health authorities.

A thorough reading and analysis of the FCA's decision shows that the latter, while recognizing that the off-label use of Avastin was highly debated in the scientific community at the time of the alleged practices, decided to confront the content of Roche and Novartis' communications with the French health authorities on the risks associated with such off-label in light of the FCA's own interpretation of the facts. This approach, which is highly debatable and currently being challenged before the Paris Court of Appeal, is nonetheless illustrative of the more aggressive intervention of competition authorities in the pharmaceutical sector.

This new trend should, however, not make pharmaceutical companies forget about other types of conduct based on pricing strategies (such as predatory pricing or loyalty-inducing rebate schemes) that have classically been considered as raising competition issues in the sector. In this respect, following an already steady pace of enforcement in 2020, there have been several additional decisions adopted over the last 12 months. The Dutch Competition Authority, for example, closed an investigation against AbbVie in exchange for the latter's commitments to put an end to a discount policy that was leading hospitals to purchase exclusively (or mostly) AbbVie's product Humira, therefore preventing the entry of biosimilars. [*31*] In Austria, Merck Sharp & Dohme (MSD) GmbH offered commitments in March 2021 to remedy concerns of the authority over a potential predatory pricing strategy concerning its drug Temodal® (used as a chemotherapy in the treatment of brain cancer). MSD was suspected of selling Temodal® to hospitals below costs (in addition to providing free samples), thereby preventing generic entry or forcing competitors out of the market [*32*].

III. Excessive pricing

Excessive pricing issues have been a particular focus of discussion over the past years, giving rise to a series of complaints, investigations and decisions throughout the EU. Most of this activity has been at the national level, where NCAs have been at the forefront of enforcement. There has, however, also been activity at the EU level with the recent adoption, in February 2021, of the long-awaited Commission's decision in the Aspen case, the first one on excessive pricing in the pharmaceutical sector [*33*].

The Commission's intervention follows an investigation that started in Italy, which resulted in Aspen being sanctioned in 2016 with a fine of 5.2 million euros for having charged excessive prices for some essential off-patent cancer drugs it had acquired from GlaxoSmithKline (the "**Cosmos drugs**"). [*34*] As other Member States expressed concerns regarding comparable practices by Aspen in their respective jurisdictions, the Commission decided to open an investigation against Aspen in May 2017 for an alleged abuse of dominant position in the form of excessive pricing, covering all Member States except Italy. During its investigation, the Commission

expressed concerns that Aspen devised a pan-European strategy to impose, without any objective justification, significant price increases on national health systems for the Cosmos drugs. Such strategy was based on three pillars:

- first, a sequenced implementation throughout the EU in order to circumvent the purpose and functioning of the external reference pricing system which, by way of reminder, allows national health authorities to fix the price of a given drug by taking into account the price of that same drug in other Member States;
- second, retaliation measures to overcome the potential resistance of national health authorities, including threats of or, in some cases, actual de-listings and withdrawals of the concerned drugs from the market; and
- third, the implementation of a stock allocation system that prevented, or at least limited, parallel trade between Member States. According to the Commission's preliminary findings, Aspen derived unusually large profits from the price increases, achieving margins ranging between 70 and 90%. By comparison, prior to 2012, Aspen's margins reached a maximum of 40-50% and the median margins of comparators (i.e., companies selling drugs having a similar profile to that of the product concerned) was on average less than 50%. In addition, the Commission reached the preliminary conclusion that there were no legitimate reasons justifying the price increases imposed by Aspen, since the latter reflected neither any specific risk-taking nor innovation, investment or material improvement in the products. The Commission also took into account the fact that Aspen, which was aware of the critical importance of the drugs for patients and the absence of any alternative, used this as a leverage against health authorities to impose price hikes that it may not have otherwise obtained.

In the above assessment, the Commission applied the standard two-limb test set by the ECJ in the*United Brands* case, [***35***] which consists of determining 1) whether the difference between the costs actually incurred and the price actually charged is excessive, and 2) if so, whether the price is unfair within the meaning of Article 102 of the TFEU, either in itself or in comparison with competing products, these two conditions being alternatives. The Commission, however, acknowledged that several methods may be used to characterize the imposition of an unfair price in the form of excessive pricing, and that it is for the competition authority to select the most appropriate method in each case.

Quite surprisingly, the Commission ultimately chose to close the case with a commitment decision, thereby avoiding having to characterize an infringement of competition law. Aspen indeed offered a series of commitments to remedy the Commission's concerns, which the latter accepted and made binding pursuant to Article 9§1 of Regulation 1/2003. Such commitments consist of:

- reducing the net prices for each of the products concerned in all Member States by, on average, 73%, with the new prices corresponding to maximum prices for the next ten years; it is worth noting that the price reductions will apply retroactively as from October 2019, with Aspen having to reimburse national health systems the difference in price for the transitory period between October 2019 and the actual implementation of the price decrease; and
- supplying the products for at least five years and then, for an additional period of five years, either continue to do so or, should Aspen decide to discontinue the commercialization in one or several Member States, give a 12 months' notice to health authorities and make the marketing authorization available for sale to any interested third party.

This result benefits Aspen which not only got off without a fine but may now also steer clear of private actions for damages (as potential victims seeking to obtain damages will have to first prove an infringement of competition law, which is not easy and probably even more difficult in excessive pricing cases).

At the Member States' level, the Dutch, Italian and Spanish competition authorities have been investigating the behavior of Lediant Biosciences in their respective territories, following complaints that the company charged excessive prices for the drug chenodeoxycholic acid (CDCA), used for the treatment of a rare metabolic disorder called cerebrotendineous xanthomatosis (or CTX).

While the case is still pending in Italy and Spain, the Dutch Authority for Consumers & Markets (**ACM**") has recently closed its investigation imposing a fine of 19.5 million euros on Leadiant [***36***]. The ACM found that the group implemented a sequenced strategy to impose several significant price increases for CDCA: first, after acquiring the CDCA treatment from another manufacturer, Lediant increased the price from 46 euros for a pack of 100 capsules to 885 euros; then, after obtaining that CDCA be granted the status of orphan drug, the price was set at 3,103 euros. Eventually, when Lediant was granted a marketing authorization for a second CDCA-based drug – that however did not differ from the first one, which it discontinued – the treatment for CTX reached 14,000 euros in the Netherlands.

Another important source of guidance on excessive pricing remains the CMA's decisional practice which, although the UK is no longer part of the EU, is so far the most detailed. The question of how to characterize an excessive and unfair price indeed gave rise to an intense legal debate in the *Pfizer / Flynn* case which is now back before the CMA.

In September 2016, the CMA fined Pfizer and Flynn Pharma £84.2 million and £5.2 million respectively for having charged excessive prices (representing an increase of 2,600 percent) for the supply of a mature anti-epileptic drug, Epanutin® (phenytoin capsules). [***37***] The CMA's decision was initially quashed by the CAT as the latter considered that the CMA failed to correctly apply the *United Brand* test because "*it did not appropriately consider what was the right economic value for the product at issue; and it did not take sufficient account of the situation of other, comparable products, in particular of the phenytoin sodium tablet*", sold at a lower price. [***38***] The Court of Appeal upheld for the most part the ruling of the CAT, but also recalled – as the Commission did in the *Aspen* case – that competition authorities benefit from a certain freedom when defining the method they see fit to establish the excessiveness of a price. However, the Court noted that authorities should also take into consideration the methods and evidence brought forward by the parties in their defense. [***39***]

The case was therefore remitted to the CMA, which provisionally adopted the same position in a new statement of objections issued on 5 August 2021, which accuses Pfizer and Flynn of infringing competition law by imposing excessive prices for phenytoin sodium capsules. Pfizer and Flynn will now have the possibility to respond and challenge again the findings and methods of the CMA.

The CMA also adopted two other decisions relating to excessive pricing practices over the summer of 2021. First, on 15 July 2021, the authority fined Auden McKenzie and Actavis UK (now Accord-UK) £260 million for imposing excessive prices on hydrocortisone tablets, used for the treatment of adrenal insufficiency, and paying their competitors to stay out of the market. [***40***]. Second, on 29 July 2021, Advanz and its previous owners (two private equity firms) were fined over £100 million for having imposed a 1,110% increase of the price of liothyronine tablets used to treat thyroid deficiency. [***41***] In both cases, the companies used the "flaws" of the law to exit the regulated market and freely set high prices for medicines that they knew were indispensable to patients.

Eventually, the CMA also closed an investigation in December 2020, two months after its launch, against Essential Pharma by accepting the commitments of the company. [*42*] Essential Pharma supplies two treatments for bipolar disorder based on lithium carbonate: Priadel and Camcolit. The CMA suspected Essential Pharma of an abuse of dominant position on the market for lithium carbonate medicines based on its consideration of withdrawing Priadel from the UK market to either secure a price increase for Priadel or force the switch of patients to a more expensive drug, Camcolit. The company committed to ensure the continuity of the supply of Priadel in the national market for the next five years.

Conclusion

The pharmaceutical sector seems to be a bottomless pit for competition authorities, which every year continue to closely monitor the industry and are never short of novel theories to tackle market behaviors which they consider anticompetitive. The one exception is perhaps Germany where, rather surprisingly, the pharmaceutical sector does not seem to constitute a top enforcement priority for the antitrust authorities.

Dominant companies, which by way of reminder are under a special responsibility not to hinder, by their conduct, genuine competition on the market, therefore need to be very careful, even more so today as the scope of intervention of competition authorities seems to progressively increase. Any conduct – whichever the form, including through the acquisition of a rival firm – potentially restricting innovation or preventing price decreases, can nowadays attract antitrust scrutiny and result in significant fines.

In addition to the above developments, one must also not forget the numerous sector inquiries that regularly target the pharmaceutical industry and whose findings may give rise to subsequent investigations, as was the case at the EU level with the pay-for-delay cases. Just this past year, the Czech competition authority launched a sector inquiry into the distribution of prescription drugs and medicines covered by the public health insurance in June 2021. [*43*] The Austrian Federal Competition Authority ("**AFCA**"), after launching a sector inquiry in 2017, published its third interim report in May 2021, in which it expressed concerns about parallel trade as well as the growing concentration in the sector, both factors contributing, in its view, to potential medicine shortages. [*44*] Another example of NCAs scrutiny can be found in Greece, where the Hellenic Competition Commission announced on 7 October 2021 that it had raided the premises of a company active in the manufacture and supply of pharmaceuticals for potential abuse of dominance. [*45*] It will be interesting to follow these developments in 2022.

It is also worth recalling that the attention given to the sector has somewhat increased since the beginning of the pandemic. On the one hand, competition authorities have shown more flexibility in the application of competition rules to enable certain essential collaborations for the production and supply of critical products. In this context, the European Commission issued its second comfort letter in March 2021 for an online event dedicated to responding to the demand for COVID-19 vaccines, in order for participants to find partners with complementary capabilities. [*46*] On the other hand, antitrust enforcement has not been relaxed. Some NCAs received hundreds of complaints alleging excessive prices for different products used in the fight against the pandemic (e.g. sanitizer, masks, etc.), leading to several investigations being opened. For example, the Polish competition authority opened an investigation concerning the supply of oxygen to hospitals, suspecting an abuse of dominance of the few companies active in this market in Poland. [*47*]

Finally, although precedents are still scarce, follow-on claims for damages have started to develop in the pharmaceutical sector, notably in the UK and Italy, but also in France where, for example, the national health security is currently seeking to recover damages from Sanofi in the Plavix case. The Paris Court of Appeal is

expected to issue its judgment soon and will have to decide whether – as retained by the first instance court – the action was time-barred. Private enforcement will most probably continue to further develop in the future as a complementary tool to public enforcement, thus exposing pharmaceutical companies to additional risks under competition law.

Note from the Editors: although the e-Competitions editors are doing their best to build a comprehensive set of the leading EU and national antitrust cases, the completeness of the database cannot be guaranteed. The present foreword seeks to provide readers with a view of the existing trends based primarily on cases reported in e-Competitions. Readers are welcome to bring any other relevant cases to the attention of the editors.

[*1*] See *https://ec.europa.eu/health/sites/default/files/human-use/docs/pharmastrategy_com2020-761_en.pdf*, ***Peter L'Ecluse, Catherine Longeval, Koen T'Syen***, *The EU Commission presents the pharmaceutical strategy for Europe, 25 November 2020, e-Competitions November 2020, Art. N° 98056.*

[*2*] European Commission, Press release of 16 March 2021, *Competition: The European Commission forms a Multilateral Working Group with leading competition authorities to exchange best practices on pharmaceutical mergers* ; FTC, Press release of 16 March 2021, *FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers* ; See ***Catherine Gordley,*** *The EU Commission and other Competition Authorities announce the formation of a multilateral pharma merger working group, 16 March 2021, e-Competitions March 2021, Art. N° 100100* ; ***Karen M. Lent, Kenneth B. Schwartz,*** *The US FTC announces a multilateral working group to build a new approach to pharmaceutical mergers, 16 March 2021, e-Competitions March 2021, Art. N° 100476* ; ***European Commission,*** *The EU Commission forms a multilateral working group with leading competition authorities to exchange best practices on pharmaceutical mergers, 16 March 2021, e-Competitions February 2021, Art. N° 99702.*

[*3*] European Commission, Decision No. C(2021) 1959 final of 26 March 2021, *Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases* ; See ***Matthew G. Rose, Douglas Lahnborg, Saira Henry, Marie-Laure Combet,*** *The EU Commission publishes guidance and expands its jurisdiction by capturing transactions below the jurisdictional thresholds of national and EU merger control regimes, 26 March 2021, e-Competitions March 2021, Art. N° 100046* ; ***Philippe-Emmanuel Partsch, Fynn Dewald, Joe Zeaiter,*** *The EU Commission publishes guidance on the application of the referral mechanism set out in article 22 of the Merger Regulation to certain categories of cases, 26 March 2021, e-Competitions March 2021, Art. N° 100901* ; ***Hendrik Viaene, David Henry,*** *The EU Commission publishes guidance on the application of the referral mechanism set out in article 22 of the merger regulation to certain categories of cases, 26 March 2021, e-Competitions March 2021, Art. N° 100094.*

[*4*] European Commission, Press release of 22 July 2021, Mergers: Commission opens in-depth investigation into proposed acquisition of GRAIL by Illumina ; See ***European Commission,*** *The EU Commission opens an in-depth investigation into a proposed merger between two genomics companies (Grail / Illumina), 22 July 2021, e-Competitions July 2021, Art. N° 101724.*

[*5*] General Court, Application of 28 April 2021, *Grail / Illumina*, Case T-227/21.

[*6*] See ***European Commission***, *The EU Commission starts an investigation for possible breach of a standstill obligation in a merger between two biotechnology and pharmaceutical companies (Grail / Illumina), 20 August 2021, e-Competitions August 2021, Art. N° 102103*, ***Michael Clancy, Peter L'Ecluse, Catherine Longeval, Koen T'Syen***, *The EU Commission opens a new front by investigating a possible violation of a standstill obligation under the EU Merger Regulation against a concentration that is below usual EU and national thresholds for review (Grail / Illumina), 20 August 2021, e-Competitions August 2021, Art. N° 102431.*

[*7*] European Commission, Press release of 29 October 2021, *Grail / Illumina* ; See ***European Commission***, *The EU Commission adopts interim measures to prevent harm to competition following a merger between biological and pharmaceutical companies (Grail / Illumina), 29 October 2021, e-Competitions October 2021, Art. N° 103224*, ***Michael Clancy, Peter L'Ecluse, Catherine Longeval, Koen T'Syen***, *The EU Commission announces interim measures to avert possibly irreversible consequences of a merger between two pharmaceutical companies (Grail / Illumina), 29 October 2021, e-Competitions October 2021, Art. N° 103345*

[*8*] General Court, Order of the President of the third chamber of 6 October 2021, *Grail / Illumina*, Case T-227/21.

[*9*] ECJ, Judgement of 25 March 2021, *Lundbeck*, Case C-591/16 P ; See ***Enzo Marasà, Irene Picciano, Marianna Riedo,*** *The EU Court of Justice confirms the General Court's judgment and Commission's decision on pharmaceutical pay-for-delay agreements (Lundbeck), 25 March 2021, e-Competitions March 2021, Art. N° 100409* ; ***Elena Wiese, Florian von Schreitter,*** *The EU Court of Justice confirms the decision of the Commission to impose fines on several pharmaceutical companies (Lundbeck), 25 March 2021, e-Competitions March 2021, Art. N° 100431* ; ***Marilena Nteve, Wesley Lepla, Miranda Cole,*** *The EU Court of Justice dismisses the appeals of several manufacturers of medicines against the General Court's judgment upholding the Commission's pay-for-delay infringement decision (Lundbeck), 25 March 2021, e-Competitions March 2021, Art. N° 100265.*

[*10*] ECJ, Judgment of 30 January 2020, *Generics UK*, Case C-307/18. See, ***Sandrine Mathieu, Amélie Lamarcq***, *The EU Court of Justice clarifies the conditions under which pay-for-delay agreements preventing generic versions of a patented medicine from entering the market or delaying such entry may constitute a restriction of competition 'by object' or 'by effect' as well as an abuse of dominant position (Generics - UK / GlaxoSmithKline / Actavis / Xellia Pharmaceuticals / Merck / Alpharma), 30 January 2020, e-Competitions January 2020, Art. N° 94657*, ***Kyriakos Fountoukakos, Dafni Katrana, Ruth Allen***, *The EU Court of Justice clarifies the criteria for the pay-for-delay agreements in the pharmaceutical sector (Generics - UK / GlaxoSmithKline / Actavis / Xellia Pharmaceuticals / Merck / Alpharma), 30 January 2020, e-Competitions January 2020, Art. N° 93498*, and ***Catriona Hatton, Paul Lugard, Daniel Vasbeck***, *The EU Court of Justice clarifies for the first time when patent settlement agreements restricting a generic pharmaceutical company's ability to enter the market infringes the EU antitrust rules (Generics - UK / GlaxoSmithKline / Actavis / Xellia Pharmaceuticals / Merck / Alpharma), 30 January 2020, e-Competitions January 2020, Art. N° 93745.*

[*11*] EVP Margrethe Vestager's speech at Fordham International Antitrust law and Policy Conference, New York, 1st October 2021.

[*12*] General Court, Judgment of 12 December 2018, *Servier*, Case T-691/14 ; See, ***Sophie Pele, Mélanie Thill-Tayara, Marion Provost, Simon Hetsch***, *The EU General Court annuls a decision of the Commission for wrongly qualifying agreements as 'pay for delay' and improperly qualifying an abuse of dominance, thus reducing the fine imposed on a pharmaceutical company (Servier), 12*

December 2018, e-Competitions December 2018, Art. N° 88946, ***Enzo Marasà***, *The EU General Court holds that patent settlements may be deemed pay-for-delay agreements only if there are reverse payments, and the originator may not be held dominant if the market is not assessed rigorously (Servier), 12 December 2018, e-Competitions December 2018, Art. N° 90103*, and ***James Aitken, Christopher Stothers, Gian Luca Zampa***, *The EU General Court rules that pay-for-delay patent settlements can be illegal agreements but annuls abuse of dominance finding (Servier), 12 December 2018, e-Competitions December 2018, Art. N° 94166.*

[***13***] Ibid., § 1393.

[***14***] Ibid., § 1395.

[***15***] Pending cases C-176/19 P and C-201/19 P; oral hearing on 21 October 2021.

[***16***] ECJ, Judgement of 30 January 2020, *Generics UK*, case No. C-307/18. See note 4 above.

[***17***] CAT, 10 May 2021, *Generics (UK) Ltd, GlaxoSmithKline Plc v. CMA*, Case Nos: 1251-1255/1/12/16. See ***UK Competition Authority***, *The UK Competition Appeal Tribunal upholds an infringement decision for pay-for-delay pharmaceutical deals (GlaxoSmithKline), 10 May 2021, e-Competitions May 2021, Art. N° 100779*, ***Steven Vaz, Edward McNeill***, *The UK Competition Appeal Tribunal confirms infringement in paroxetine pay-for-delay case but slashes fines (GlaxoSmithKline), 10 May 2021, e-Competitions May 2021, Art. N° 101221*, and ***Samuel Hall***, *The UK Competition Appeal Tribunal confirms a pay-for-delay infringement decision but reduces the fines inflicted (GlaxoSmithKline), 10 May 2021, e-Competitions May 2021, Art. N° 101271.*

[***18***] ECJ, Judgment of 23 January 2018, *Hoffmann-La Roche*, Case 179/16 ; See ***Enzo Marasà, Eugenio Foco,*** *The EU Court of Justice holds that colluding to disseminate information constitute a restriction of competition "by object" (Hoffman-La Roche / Novartis), 23 January 2018, e-Competitions January 2018, Art. N° 90104* ; ***Philip Bentley, Jacques Buhart, Mai Muto,*** *The EU Court of Justice clarifies the application of competition law to the pharmaceutical sector in relation to off-label use of medicine and the dissemination of misleading information about product characteristics (Hoffman-La Roche / Novartis), 23 January 2018, e-Competitions January 2018, Art. N° 89592* ; ***Floriane Aufaure, Ombline Ancelin,*** *The EU Court of Justice rules that the dissemination of misleading information is a restriction by object and excludes exemption under Article 101 §3 TFEU (Hoffman-La Roche / Novartis), 23 January 2018, e-Competitions January 2018, Art. N° 86139.*

[***19***] ECJ, Request for a preliminary ruling from the Consiglio di Stato of 21 April 2021, *Hoffman-La Roche / Novartis*, Case C-261/21

[***20***] FCA, Decision No. 20-D-11 of 9 September 2020, *Novartis / Roche / Genentech* ; See ***Samuel Hall,*** *The French Competition Authority fines 3 laboratories for abusive efforts to segment the market (Novartis / Roche / Genentech), 9 September 2020, e-Competitions September 2020, Art. N° 97142* ; ***Michaël Cousin,*** *The French Competition Authority imposes a fine worth a total of €444 million on three pharmaceutical companies for collective abuse of dominance practices designed to sustain the sale of an expensive drug (Novartis / Roche / Genentech), 9 September 2020, e-Competitions September 2020, Art. N° 96958* ; ***French Competition Authority,*** *The French Competition Authority fines three laboratories for abusive practices (Novartis / Roche / Genentech), 9 September 2020, e-Competitions September 2020, Art. N° 96662.*

[***21***] European Commission, Staff Working Paper of 9 December 1997, *Commission staff working*

document evaluation of the commission notice on the definition of relevant market for the purposes of community competition law ; European Commission, Press release of 12 July 2021, *Commission publishes findings of evaluation of Market Definition Notice* ; See ***European Commission,*** *The EU Commission publishes the findings of its evaluation of the Market Definition Notice, 12 July 2021, e-Competitions July 2021, Art. N° 101516.*

[***22***] European Commission, Decision of 26 November 2020, *Teva / Cephalon*, Case AT.39686 ; See ***Duncan Liddell, Steven Vaz,*** *The EU Commission fines pharmaceutical companies for pay-for-delay agreement (Teva / Cephalon), 26 November 2020, e-Competitions November 2020, Art. N° 98232* ; ***Peter L'Ecluse, Catherine Longeval, Koen T'Syen,*** *The EU Commission fines two pharmaceutical companies for pay-for-delay patent settlement agreement (Teva / Cephalon), 26 November 2020, e-Competitions November 2020, Art. N° 98080* ; ***European Commission,*** *The EU Commission fines two pharmaceutical companies €60.5 million for delaying the entry of cheaper generic medicine for sleep disorders (Teva / Cephalon), 26 November 2020, e-Competitions November 2020, Art. N° 98256.*

[***23***] See ***European Commission***, *The EU Commission opens a formal investigation into possible anticompetitive conduct of a global pharmaceutical company concerning a blockbuster multiple sclerosis medicine (Teva), 4 March 2021, e-Competitions February 2021, Art. N° 99610*, and ***Kyriakos Fountoukakos, Sebastien Moore, Kristien Geeurickx*** , *The EU Commission investigates for the first time a case relating to divisional patent filing and litigation strategies in the pharmaceutical sector (Teva), 4 March 2021, e-Competitions February 2021, Art. N° 99604.*

[***24***] Italian Council of State, Decision no. 693/214, 2014. See ***Gabriele Accardo***, *The Italian Council of State reinstates penalties against a company for an abuse of dominant position to artificially extend the patent protection (Pfizer), 12 February 2014, e-Competitions February 2014, Art. N° 64803.*

[***25***] European Commission, Decision of 15 June 2005, *AstraZeneca*, Case A.37507/F3, confirmed by General Court, Judgment of 1st July 2010, Case T-321/05 and ECJ, Judgment of 6 December 2012, Case C-457/10. See ***Søren Bo Rasmussen, Niklas Fagerlund***, *The EU Commission imposes a €60 million fine against two companies in the pharmaceutical sector for abuse of dominant position (AstraZeneca), 15 June 2005, e-Competitions June 2005, Art. N° 36764*, ***Thomas Graf***, *The EU General Court fines a company for abuse of a dominant position in the pharmaceutical sector addressing the issues of market definition and dominance analysis (AstraZeneca), 1 July 2010, e-Competitions July 2010, Art. N° 35645*, and ***Emanuela Matei***, *The EU Court of Justice entirely dismisses pharmaceutical company's appeal on abusive patent misuse (AstraZeneca), 6 December 2012, e-Competitions December 2012, Art. N° 50294.*

[***26***] See *AstraZeneca* case mentioned above or *F. Hoffmann-La Roche* v. AGCM mentioned below.

[***27***] FCA, decision No. 13-D-11 of 14 May 2013, upheld on appeal and confirmed by the French Supreme Court. See ***Joseph Vogel***, *The French Competition Authority fines a pharmaceutical company for disparaging competing generics (Sanofi-Aventis), 14 May 2013, e-Competitions May 2013, Art. N° 52523.*

[***28***] FCA, decision No. 17-D-25 of 20 December 2017, partially confirmed on appeal. See ***French Competition Authority***, *The French Competition Authority fines €25 million a pharmaceutical laboratory for having first prevented then restricted the development of generic versions of a drug (Janssen-Cilag / Johnson & Johnson), 20 December 2017, e-Competitions December 2017, Art. N° 85529.*

[*29*] Paris Court of Appeal, Judgment of 11 July 2019. See ***Mélanie Thill-Tayara, Marion Provost, Sophie Mitouard***, *The Paris Court of Appeal upholds the decision of the Competition Authority to fine a pharma company for abuse of dominance (Jansson-Cilag / Johnson & Johnson), 11 July 2019, e-Competitions July 2019, Art. N° 96202*.

[*30*] FCA, decision No. 20-D-11 of 9 September 2020. See ***French Competition Authority***, *The French Competition Authority fines three laboratories for abusive practices (Novartis / Roche / Genentech), 9 September 2020, e-Competitions September 2020, Art. N° 96662*, ***Michaël Cousin***, *The French Competition Authority imposes a fine worth a total of €444 million on three pharmaceutical companies for collective abuse of dominance practices designed to sustain the sale of an expensive drug (Novartis / Roche / Genentech), 9 September 2020, e-Competitions September 2020, Art. N° 96958*.

[*31*] See ***Dutch Competition Authority***, *The Dutch Competition Authority closes its investigation into a drug manufacturer after receiving assurances that it will not use its discount schemes to force hospitals into exclusive purchases (AbbVie), 24 September 2020, e-Competitions September 2020, Art. N° 96990*.

[*32*] See ***Michael Clancy, Samuel Hall, Peter L'Ecluse, Catherine Longeval, Koen T'Syen,*** *The Austrian Competition Authority accepts commitments and closes its pharmaceutical pricing investigation on the sale of a brain tumor treatment (Merck Sharp / Dohme), 2 April 2021, e-Competitions March 2021, Art. N° 100281* ; MLex, 2 April 2021, MSD agrees to stop aggressive pricing for cancer drug in Austria.

[*33*] European Commission, Decision of 10 February 2021, *Aspen*, Case AT.40394 ; See ***Kyriakos Fountoukakos, Max Kaufman, Kristien Geeurickx, Agathe Célarié,*** *The EU Commission accepts the commitment offered by a pharmaceutical company to reduce drug prices by 73% (Aspen), 10 February 2021, e-Competitions February 2021, Art. N° 99565* ; ***Donald Slater,*** *The EU Commission accepts commitments from a pharmaceutical company to address excessive pricing (Aspen), 10 February 2021, e-Competitions February 2021, Art. N° 99613* ; ***Michael Clancy, Samuel Hall,*** *The EU Commission accepts the commitment offered by a pharmaceutical company for excessive pricing (Aspen), 10 February 2021, e-Competitions February 2021, Art. N° 100835*.

[*34*] AGCM, 29 September 2016, Aspen Pharma Trading Ltd., Aspen Italia s.r.l., Aspen Pharma Ireland Ltd., Aspen Pharmacare Holdings Ltd, case A. 480. See ***Michele Giannino***, *The Italian Competition Authority fines a generic manufacturer of drugs for excessive pricing (Aspen), 29 September 2016, e-Competitions September 2016, Art. N° 81747*. Decision upheld by the Regional Administrative Court for Latium, First Chamber, Aspen Pharma Trading Ltd et al. v. Autorità Garante della Concorrenza e del Mercado (Aspen v. AGCM), 6 July 2017, case no. 12806/2016. See ***Michele Giannino***, *The Italian Regional Administrative Court for Latium upholds the infringement decision made by the Competition Authority against a pharmaceutical laboratory for excessive pricing (Aspen), 26 July 2017, e-Competitions July 2017, Art. N° 84682*.

[*35*] ECJ, 14 February 1978, *United Brands Company and United Brands Continentaal BV v Commission*, case 27/76.

[*36*] ACM, Press release of 19 July 2021, *ACM imposes fine on drug manufacturer Leadiant for CDCA's excessive price* ; See ***Samuel Hall, Michael Clancy, Peter L'Ecluse,*** *The Dutch Competition Authority fines a medicine supplier almost €20 million for excessive pricing of a metabolic disorder medicine (Leadiant), 20 July 2021, e-Competitions July 2021, Art. N° 101930* ; ***Pauline Kuipers, Joost van Roosmalen,*** *The Dutch Competition Authority imposes a fine totaling €20 million on an orphan drug manufacturer for excessive pricing (Leadiant), 20 July 2021, e-*

Competitions July 2021, Art. N° 103229 ; ***Dutch Competition Authority,*** *The Dutch Competition Authority fines a national drug manufacturer for excessive pricing (Leadiant), 20 July 2021, e-Competitions July 2021, Art. N° 102185.*

[***37***] CMA, 7 December 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, Case No. CE/9742-13. See ***UK Competition Authority***, *The UK Competition Authority fines two pharmaceutical companies for charging excessive prices concerning an anti-epilepsy drug (Pfizer / Flynn), 7 December 2016, e-Competitions December 2016, Art. N° 82459.*

[***38***] CAT, Judgement of 7 June 2018, *Flynn Pharma Ltd and Pfizer Inc. v. CMA*, Case Nos: 1275-1276/1/12/17, §4 ; See ***Ian Giles, Clio Angeli***, *The UK Competition Appeal Tribunal partly annuls the Competition Authority's decision that pharmaceutical companies abused their dominant position by setting excessive and unfair prices for an epilepsy drug (Pfizer / Flynn), 7 June 2018, e-Competitions June 2018, Art. N° 90012.*

[***39***] Court of Appeal, Judgement of 10 March 2020, *Competition and Markets Authority v. Flynn Pharma Limited and Pfizer Inc.*, Case No: C3/2018/1847 & 1874 ; See ***Matthew Hunt, Stephen Smith***, *The UK Court of Appeal of England and Wales considers the test for excessive pricing after an undertaking had charged unfairly high prices for phenytoin sodium capsules (Pfizer / Flynn), 10 March 2020, e-Competitions March 2020, Art. N° 93661*, ***Ingrid Vandenborre, Caroline Janssens***, *The UK Court of Appeal of England and Wales imposes agency discretion in the methodology to establish the unfairness of prices, thereby increasing the burden of proof on companies to avoid a finding of excessive pricing (Pfizer / Flynn), 10 March 2020, e-Competitions March 2020, Art. N° 94086*, and ***James Killick, Assimakis Komninos, Aqeel Kadri***, *The UK Court of Appeal of England and Wales upholds the Competition Appeal Tribunal's quashing of the Competition Authority's decision against pharmaceutical undertakings who had allegedly abused their dominant position by pricing their epilepsy drug unfairly (Pfizer / Flynn), 10 March 2020, e-Competitions March 2020, Art. N° 94178.*

[***40***] CMA, Decision of 15 July 2021, *Unfair pricing abuses and anti-competitive agreements in relation to 10mg and 20mg hydrocortisone tablets*, Case 50277 ; See ***UK Competition Authority***, *The UK Competition Authority fines two drug companies for overcharging the National Health Service (Auden Mckenzie / Actavis), 15 July 2021, e-Competitions July 2021, Art. N° 101627.* Auden Mckenzie/Actavis UK, Waymade and AMCo were also found to have infringed the UK equivalent of Article 101 by entering into agreements whose object was to prevent competition on the hydrocortisone tablets market.

[***41***] CMA, Decision of 29 July 2021, *Unfair pricing abuse in relation to Liothyronine tablets* ; See ***UK Competition Authority***, *The UK Competition Authority fines a pharmaceutical company for overinflating the price of thyroid tablets (Advanz), 29 July 2021, e-Competitions July 2021, Art. N° 101890.*

[***42***] CMA, decision of 18 December 2020 to accept commitments offered by Essential Pharma in relation to the supply of Priadel, Case No. 50951 ; See ***UK Competition Authority***, *The UK Competition Authority accepts legally binding commitments from a pharmaceutical company to secure the affordable supply of a key drug (Essential Pharma), 18 December 2020, e-Competitions December 2020, Art. N° 98528.*

[***43***] See ***Vojtech Chloupek, Jiři Švejda***, *The Czech Competition Authority initiates a pharmaceutical sector inquiry, 8 June 2021, e-Competitions June 2021, Art. N° 101163* ; MLex, 8 June 2021, Czech pharma distribution: watchdog opens sector inquiry.

[*44*] Austrian Federal Competition Authority, Sector Inquiry Health, The Supply of Medicines from a competition perspective, March 2021.

[*45*] Hellenic Republic Competition Commission, Press Release, 7 October 2021.

[*46*] Comfort letter: cooperation at a Matchmaking Event – Towards COVID-19 vaccines upscale production, 25 March 2021, COMP/E-1/GVBV/nb (2021/034147).

[*47*] See ***Polish Competition Authority***, *The Polish Competition Authority President initiates an investigation into the market of oxygen supply to hospitals, 17 November 2020, e-Competitions November 2020, Art. N° 97986.*