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

UNILATERAL PRACTICES, ABUSE OF DOMINANCE, DOMINANCE, REFUSAL TO DEAL, PARALLEL IMPORTS, FOREWORD, DOMINANCE (NOTION), PAY-FOR-DELAY

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The pharmaceutical sector stands out as being regularly on the radar of competition authorities throughout Europe, with no less than 7 decisions adopted within the last 18 months and multiple on-going investigations, covering a wide range of practices, from excessive pricing to pay for delay, refusal to supply and, more generally, commercial strategies implemented by pharmaceutical companies to delay generic or biosimilar entry.

Most recently, the French Competition Authority ("**FCA**") has launched a new sector enquiry into the pharmaceutical sector [*1*], less than . ve years after it issued a first opinion in 2013 [*2*]. The FCA is currently focusing on the drug distribution chain, a topic which was already covered in its previous probe, and will also, for the first time, look into price regulation mechanisms in the industry. It should issue its conclusions with the adoption of two different opinions, the first one by the end of 2018 and the second one in the course of the first half of 2019.

Against this background, this article will describe the most recent developments in the sector, focusing on abuses of dominant position cases. Originator companies are particularly exposed to this type of infringement because, after the period during which they enjoy patent protection, they need to adapt to the potential arrival of competition on the market.

Three broad types of practices have been targeted by competition authorities in recent matters: excessive pricing, which has recently caught the attention of various regulators in Europe (**I.**); the use of patents by originator companies to delay generic entry (**II.**); and disparagement of competing drugs to health professionals and health authorities, with a view to instill a doubt about potential risks associated with the use of generic or biosimilar drugs instead of the reference medicine (**III.**). Refusal to supply to combat parallel trade has also recently resurfaced, with one notable decision from the Greek regulator (**IV.**).

I.Excessive pricing

Article 102 of the Treaty on the Functioning of the European Union ("**TFEU**") expressly targets the direct or indirect imposition of unfair prices or trading conditions as a type of abuse. While for many years the Commission and national competition authorities have been rather reluctant to make use of that provision against allegedly high prices imposed by dominant firms [***3***], both have recently shown a renewed and growing interest in pursuing excessive pricing cases in the pharmaceutical sector, with enforcement clearly being on the rise since 2016. By contrast, in the US, excessive prices are not, as such, considered as unlawful [***4***]. The view of the courts is rather that denying legitimately-obtained profits to a monopolist may diminish its incentives to innovate.

The classic European case first establishing the test for what constitutes excessive pricing is *United Brands* ***[5]***, where the European Court of Justice ("**ECJ**") defined two necessary criteria: (1) determining whether the difference between the costs incurred by the dominant firm and the price actually charged is excessive ("first limb") and, if so, (2) determining whether the price that has been imposed is either unfair in itself or when compared to competing products [***6***] ("second limb"). Although not in the pharmaceutical sector, the recent ECJ ruling of 14 September 2017 in the *AKKA* Latvian case [***7***] gave the court an opportunity to reexamine and clarify the *United Brands* test. Following the instructive and widely praised opinion of Advocate General Wahl [***8***], the ECJ insisted that several methods and benchmarks may be valid to assess the excessiveness of a price, including a comparison of prices between Member States, provided that the reference Member States are selected in accordance with objective, appropriate and verifiable criteria.

Illustrating the fact that excessive prices were until recently very rarely sanctioned, the *United Brands* test, established in 1978, was the one applied by the UK Competition and Market Authority ("**CMA**") in its 2016 *Pfizer / Flynn* decision [***9***], concerning the supply and distribution price of a mature anti-epileptic drug, Epanautin® (phenytoin capsules), which had been on the market for more than 80 years but still in use today for the treatment of epilepsy. Following the sale in 2012 by Pfizer of its marketing authorization to Flynn, the latter de-branded the product and started selling it as a generic instead, outside of any price regulation mechanism. The CMA found that the substantial overall price increase of 2,600 per cent imposed by Pfizer and Flynn constituted an abuse of dominance by both Pfizer, as manufacturer and supplier of the drug, and Flynn Pharma, as marketing authorization holder and distributor, despite the fact that the resale price was ultimately lower than the price of other anti-epilepsy drugs, notably phenytoin tablets. In September 2016, these two companies were respectively fined £84.2 million and £5.2 million.

In a rather didactic judgement handed down on 7 June 2018, the Competition Appeal Tribunal ("**CAT**") quashed the CMA's decision, considering that the latter had incorrectly applied the legal test for excessive pricing as laid down in *United Brands* ***[10]***.

Firstly, regarding the first limb of the test relating to the excessiveness of the price, the CAT considered that the CMA was wrong to rely solely on a cost-plus approach (consisting in comparing the costs incurred by Pfizer and Flynn respectively with a reasonable rate of return on the product, which was arbitrarily set at 6% by the CMA). According to the CAT, by ignoring other available methodologies, in particular failing to take into account the competitive pressure exerted by other anti-epilepsy drugs, the CMA reached a result that would have pertained in circumstances of perfect or idealized competition.

Secondly, as for the second limb of the test relating to the unfairness of the price, the CAT ruled that the CMA ought to have taken into account the evidence submitted by the parties concerning the price of the products identified as relevant comparators. Indeed, while the *United Brands* test provides for two alternatives when determining the unfairness of a price, the CAT recalled that such determination, which can be either intrinsic unfairness or in comparison to other products, ought to be made in consideration of all relevant factors and

evidence produced by the parties. In other words, according to the CAT, the CMA erred as a matter of law by concluding that the price of phenytoin capsules was unfair in itself without giving proper consideration to the arguments raised by Pfizer and Flynn concerning the price of comparative products, notably phenytoin tablets.

The last part of the CAT's analysis focused on whether the price ultimately charged bore a reasonable relation to the economic value of the product. While the CMA conducted this assessment as part of the second limb of the test, the CAT explained that this should have been done separately, as a final over-arching assessment of the existence of an infringement to competition law.

The CAT's judgement is the first one to really unravel the criteria laid down in *United Brands*, providing useful guidance on the methodology to be followed in analyzing an alleged abuse of dominant position in the form of excessive pricing. The CMA, which has been one of the most active competition authorities in cracking down on excessive drug pricing, will thus have to review its approach according to these guidelines, should the matter ultimately be remitted to it in the coming months. To avoid another disappointing outcome, these guidelines will also most probably have to be followed by the CMA in the context of its two other on-going investigations for excessive pricing, concerning Concordia and Actavis respectively. The CMA indeed issued a statement of objections on 21 November 2017 [***11***] targeting Concordia for having allegedly overcharged the National Health Security ("**NHS**") by hiking the price of its drug Liothyronine, used to treat hypothyroidism, from £4.46 in 2007 to £291 in 2017 whereas its production costs remained stable. For its part, Actavis is currently under investigation for having charged excessive and unfair prices for its hydrocortisone tablets in the UK [***12***].

Another remarkable application of the *United Brand* test was in the *Aspen* case. In 2016, the Italian competition authority ("**ICA**") found that Aspen had abused its dominant position by threatening the Italian Medicine Agency ("**AIFA**") that it would discontinue the supply of several of its anti-cancer drugs used in chemotherapy treatments (referred to as the Cosmo package), which were considered as essential and had no therapeutic alternative in Italy, if the AIFA refused to approve price increases for these products, ranging from 300 per cent to 1500 per cent. The ICA fined Aspen € 5.2 million [***13***]. Its decision was upheld by the regional administrative court for Latium in July 2017 [***14***]. In July 2018, the ICA ended its monitoring of Aspen's commitment to reduce its prices for the concerned drugs, which were retroactively decreased by approximately 80% [***15***].

Probably encouraged by its European peers, the European Commission opened its first excessive pricing case in the pharmaceutical sector in May 2017, targeting Aspen. The Commission's investigation focuses on whether Aspen has implemented throughout Europe price increases similar to those sanctioned in Italy. In the current context of uncertainty and criticism around excessive pricing cases, it will be interesting to see how the Commission will handle the issue and how much guidance it will provide.

Other competition authorities have also taken action against alleged excessive pricing schemes. The Danish Competition Council ("**DCC**") found that the Italian company CD Pharma had abused its dominant position by exploiting its position as exclusive distributor of Syntocinon, a drug used for the induction of labor, to impose excessive prices on a wholesaler, Amgros, which had no alternative source of supply [***16***]. The case is currently pending before the Attorney General for Special Economic and International Crime.

The recent multiplication of excessive pricing cases illustrates a clear shift of focus by European competition authorities in the pharmaceutical sector from exclusionary abuses to exploitative practices. More particularly, we observe that certain decisions clearly aim at fulfilling a gap or failure in regulation, leading competition authorities to act *in lieu* of health regulators. But are competition rules the appropriate tool to address such a situation?

The pursuit of excessive prices, which extends beyond the frontiers of Europe [*17*], indeed raises many legal, economic and practical questions. The general consensus among economists, lawyers and policymakers is that the intervention of competition authorities should be limited to very specific market circumstances, characterized by high barriers to entry, legal monopoly or special rights, and the absence or lack of sector specific regulation [*18*]. While the pharmaceutical industry, combining at least two of these features, seems to be particularly prone to such practices, one may however wonder whether high prices, in the absence of any other abusive conduct, call for competition authorities' intervention.

From an economic point of view, high prices represent a reward for investment. The recent increase of competition authorities' intervention to tackle alleged excessive prices, if not limited to very specific circumstances, may thus risk undermining innovation and reduce competition, which would be economically inefficient [*19*].

One may therefore hope that European competition authorities will not yield to the temptation of too quickly labeling a high price as excessive or unfair, and that the upcoming decisions will bring additional and practical guidance to the industry on the circumstances that can lead to a finding of an infringement of competition law in this area.

II. Use of patents to delay generic entry

Pharmaceutical companies enjoy patent protection on their innovative drug, which allows them to exclude others from using the patented innovation for several years, as a reward for the investment in research and development ("**R&D**"). In that context, given the costs incurred in R&D and the inevitable revenue drop when suddenly confronted with competition, the use of its patents by an originator company before actual loss of exclusivity to try delaying generic entry is hardly new.

Already in 2005, the Commission fined AstraZeneca for having allegedly abused its dominant position, notably by making misrepresentations to various national patent offices in order to maintain or obtain supplementary certificates of protection for one of its blockbuster gastrointestinal drugs, Losec, to which it was not entitled (or only for a shorter duration). As a result, generic manufacturers were prevented from entering the market [*20*].

Similarly, in 2012, the ICA fined Pfizer for having implemented a complex strategy to delay generic entry through the illegitimate use of its intellectual property rights [*21*]. Firstly, the ICA found that Pfizer had obtained a divisional patent and a supplementary certificate of protection in Italy on its blockbuster drug Xalatan, used to treat glaucoma, where the main patent expired earlier than in other countries. However, Pfizer never used this divisional patent to put a new product on the Italian market. Secondly, Pfizer warned generic manufacturers that they should stay out until the expiry of its extended patent protection, leading to several litigation and claims for damages against those which started to commercialize their drugs in spite of Pfizer's threats. Without calling into question the validity of Pfizer's intellectual property rights, the ICA considered that Pfizer's misuse of the patent system solely to delay generic entry amounted to an abuse. The ICA's decision was upheld by the Italian Council of State in 2014 [*22*].

But lately, the focus has mainly been on so-called "pay-for-delay" agreements, with the landmark European cases *Lundbeck [23]* and *Servier [24]*. While these practices are mostly pursued under Article 101 TFEU, pay-for-delay cases can also potentially include claims of an abuse of dominant position. In the *Servier* case, which is currently under appeal before the General Court [*25*], the Commission found not only that Servier entered into allegedly illegal patent settlement agreements with various generic manufacturers but, in addition, committed an abuse of dominant position by purchasing one of the only available and most advanced non-protected technologies on the market – a technology that some generic manufacturers sought to use to develop their generic version of Servier's

perindopril blood pressure control drug. The Commission noted that the technology, which was only acquired by Servier as part of a global "defense mechanism" against potential competitors, was never used and thus merely aimed at removing any potential source of alternative supply for the active ingredient perindopril. By acquiring this technology, Servier rendered an essential input which did not infringe its patents inaccessible to generic manufacturers, thereby preventing the continuation of a number of advanced generic projects and securing as a result its monopoly position on the market.

The UK paroxetine case [*26*] provides yet another example of pay-for-delay practices which were sanctioned as constituting both an infringement of Article 101 TFEU and Article 102 TFEU. In February 2016, GSK was found by the CMA to have committed an abuse of dominant position on the paroxetine market through the conclusion of three pay-for-delay agreements with generic manufacturers.

The CAT, which heard the appeals against the CMA's decision in early 2017, decided in a judgement of 8 March 2018 to refer several questions to the ECJ for a preliminary ruling. Regarding the alleged abusive conduct, the CAT essentially asks the ECJ whether and under which circumstances entering into a pay-for-delay agreement may constitute an abuse of dominant position of the patent holder within the meaning of Article 102 TFEU.

Interestingly, the CAT also asks the ECJ to provide clarifications on market definition in the context of practices which aim at delaying generic entry. Essentially, the CAT inquiredwhether, where a patented drug is substitutable with other drugs in a given therapeutic class under the ATC system [*27*], the relevant market for the purpose of assessing a potential abusive conduct by the patent holder under Article 102 TFEU consisting in preventing generic entry should include those generic products, although they cannot lawfully enter the market before expiry of the patent, provided that such patent is valid.

Whether or not "pay-for-delay" agreements should be considered an infringement of competition law is still debated amongst many in the antitrust community. As a result, further clarifications from the European courts in the coming months will certainly be most welcome.

III. Disparagement practices and unfounded intervention before health authorities

Disparagement as an abuse is, so far, a French specificity. Although not limited to the pharmaceutical sector, the recent findings of infringements by the FCA in this sector have all been disparagement cases. In particular, in the landmark *Plavix* case [*28*], the FCA fined Sanofi 40.6 million euros for having committed an abuse of dominant position consisting in discrediting generics of its blockbuster drug Plavix. The FCA, whose decision was later confirmed by the Court of Appeal and the Supreme Court, found that Sanofi had implemented a global communication strategy consisting of disseminating misleading information on the properties of generics to health authorities, with a view to instill a doubt about their bioequivalence to the originator drug.

Most recently, on 20 December 2017, the FCA issued a long awaited decision [*29*] sanctioning Janssen-Cilag ("**Janssen**", a subsidiary of Johnson & Johnson group) with a fine of 25 million euros for having abused its dominant position through the adoption of a global communication strategy targeted at health professionals, on the one hand, and health authorities, on the other hand, aimed at delaying generic entry on the French market of its blockbuster product Durogesic, an opioid with the active ingredient fentanyl used for pain relief.

In a context of insufficient knowledge of the regulatory framework and general risk aversion of health professionals, especially when prescribing strong treatments such as an opioid with a narrow therapeutic margin, the FCA notably concluded that Janssen had misused a warning message issued by the French health authority

("**ANSM**", formerly AFSSAPS) concerning the risk of switching between fentanyl specialties for certain categories of patients (notably children and the elderly), thereby providing inaccurate and incomplete information to doctors and pharmacists. More particularly, in its communication, Janssen emphasized the risks of switching from Durogesic to a generic drug when the treatment was initiated under Durogesic. This led health professionals to believe, in the FCA's view, that only the substitution of the originator drug by a generic drug was potentially dangerous whereas the ANSM's warning message targeted the potential risks associated with substitution when a patient's treatment was initiated under any fentanyl specialty without distinguishing between Durogesic and its generics.

However, the novelty of this case is the characterization of Janssen's repeated and allegedly unlawful intervention before the ANSM to delay generic entry as an abuse of dominant position. Indeed, while in its 2009 decision refusing to grant interim measures to a generic manufacturer the FCA had expressly said that the ANSM has an exclusive prerogative to appreciate the validity of Janssen's arguments pertaining to the bioequivalence of the generics with its originator drug, the FCA surprisingly took a totally different and unprecedented approach in its decision of 20 December 2017, which raises complex legal and practical issues.

More particularly, the FCA considered that the delay in granting the marketing authorization in France on the basis of the European mutual recognition procedure was due to Janssen's lobbying against the approval of generics. The FCA concluded that Janssen had used alarmist and scientifically unfounded arguments challenging the bioequivalence of generics, despite the fact such bioequivalence had already been expressly recognized by the European Commission. Janssen's intervention was found to have led the ANSM to initially block the grant of the marketing authorization, whereas, from a legal standpoint, it had no choice but to grant it, and then issuing a warning statement on substitution between Durogesic and its generics.

The FCA nonetheless failed to address the fundamental difference between the two steps in the French regulatory procedure which are (i) the granting of the marketing authorization, which the ASNM had to deliver, and (ii) the recognition of a drug as a generic version of its reference medicine through its inscription on the generics' list. This second step, which is mandatory to obtain the generic status, requires an individual scientific assessment by the ANSM in the course of which originator manufacturers could, up until the FCA's decision in the Durogesic case, engage in fairly open discussions to share their views.

The FCA's decision has been appealed to the Paris Court of Appeal. This case is, however, already very instructive in many aspects. It clearly reminds originator companies that they should be careful in all their communication on generics or biosimilars. Most importantly, it shows that the FCA no longer hesitates to intervene beyond pure competition law issues, despite its questionable competence to appropriately appreciate the validity of scientific arguments put forward by pharmaceutical companies. A similar trend seems to have emerged at the European level, where the ECJ, in its landmark *Roche / Novartis* judgement of 23 January 2018 [***30***], considered that Roche's intervention with health authorities, in which it emphasized the risks associated with the off-label use of one of its products as compared with the benefitsof a competing product used on-label, could constitute an infringement of competition law.

IV.Refusal to supply and parallel trade

Because prices of medicines are regulated on a national basis, leading to potentially significant differences among Member States, the pharmaceutical sector has always been a fertile ground for parallel trade. In the past, competition authorities have paid a particular attention to the restrictions imposed by pharmaceutical companies to

parallel trade, whether in the form of quota systems, dual pricing or refusal to supply, while at the same time recognizing the specificity of the pharmaceutical sector and the possibility for pharmaceutical companies to protect their legitimate interests.

The issue has recently resurfaced with the adoption of a sanction decision by the Hellenic Competition Commission ("**HCC**") on 11 July 2018 [***31***] regarding GSK's refusal to supply quantities to certain wholesalers. This case dates back to 2000, when GSK began limiting the sale of two of its drugs to Greek wholesalers, on the ground that quantities were exported to other EU Member States where the regulated price of these drugs was higher, thereby impacting GSK's profits. In 2003, the wholesalers complained to the HCC that GSK's refusal to sell was abusive. On appeal, a question was referred to the ECJ for a preliminary ruling, asking it to consider, in essence, whether the refusal of a dominant pharmaceutical company to meet the orders of its customers on account of the fact that such customers are involved in parallel trade could constitute an abuse within the meaning of Article 102 TFEU [***32***].

In a landmark judgment of 16 September 2008 [***33***], the ECJ, while recalling that Article 102 TFEU applies to the conduct of a pharmaceutical company which aims at restoring barriers to trade by controlling parallel exports, nonetheless tempered its position, on account of the specificity of the pharmaceutical sector, by distinguishing between ordinary and extraordinary orders. Thus, in order to protect their own commercial interests, the ECJ recognized the right to pharmaceutical companies to refuse to meet orders of its customers which can be considered as being out of the ordinary, in light of the existing business relationship and the relative size of the orders compared to the needs of the national market [***34***].

On the basis of these criteria, the HCC found that only GSK's refusal to meet ordinary orders amounted to an abuse. On the contrary, refusal to supply significant quantities of medicines destined for parallel export was not considered as abusive.

This ruling shows that certain restrictions imposed by pharmaceutical companies on parallel trade can be permitted, as long as they remain reasonable and proportionate to the underlying objective, which is to protect one's own commercial interests in a context where prices are state regulated. This echoes the approach taken by the FCA ten years ago in its decisions concerning the imposition of quota systems by certain pharmaceutical companies [***35***], in which it clearly stated that any restriction imposed on wholesalers should be limited to what is absolutely necessary to ensure a reliable and optimum supply of the national market, while at the same time preserving a certain degree of competition amongst wholesalers.

Conclusion

The past 18 months have certainly been rich in developments, and more are yet to come, whether concerning abuse of dominance cases or infringements of Article 101 TFEU.

Several companies are still under investigation by the CMA. The latter has notably sent a statement of objections to MSD in May 2017 accusing the company of having allegedly granted anticompetitive rebates to hospitals on the sale of its blockbuster drug Remicade, with a view to restrict competition from rival biosimilars that had recently entered the market. The CMA is due to take a final position on the case before the end of the year.

Following the ECJ's ruling of January 2018, the FCA has resumed its investigation into Roche and Novartis' practices concerning the off-label use of Avastin for the treatment of ocular diseases which, if the FCA follows its Italian counterpart, could potentially lead to a decision in France in the course of 2019.

The European Commission and the European courts will also be busy dealing with the *Aspen* probe, the *Teva / Cephalon* pay-for-delay case, and the appeals in *Servier* and *Lundbeck*.

Last but not least, litigation has also started to develop on the private enforcement front, especially in the UK, where several follow-on damages claims brought by the NHS are currently pending. The recent implementation of the antitrust damages directive across the EU should further facilitate the expansion of follow-on actions in the near future, laying the ground for more litigation in the pharmaceutical sector.

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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*] FCA, Decision No. 17-SOA-01 of 20 November 2017.

[*2*] FCA, Opinion No. 13-A-24 of 19 December 2013.

[*3*] For example, when Gilead increased the price of its blockbuster drug Solvadi, the Commission refused to open an investigation.

[*4*] The position of the US Federal Trade Commission and the Antitrust Division of the Department of Justice (DoJ), as explained in their contribution to the OECD Roundtable of October 2011, is rather categorical: they consider that antitrust law does not proscribe excessive pricing alone as an independent antitrust violation. However, excessive prices can be targeted under US law through other means, for example if they reflect another underlying anticompetitive practice contrary to either Section 1 or 2 of the Sherman Act. See OECD Roundtable on Excessive Prices held by the Competition Committee, US Chapter (Working Party No. 2 on Competition and Regulation), October 2011. See also "Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health", UC Irvine Law Review, Volume 6, Issue 3, pp. 281-320, December 2016.

[*5*] ECJ, Judgement of 14 February 1978, *United Brands Company c. Commission*, Case C-27/76.

[*6*] ECJ, Judgement of 14 February 1978, *United Brands Company c. Commission*, Case C-27/76, §§ 235-266.

[*7*] ECJ, Judgement of 14 September 2017, *AKKA / LAA*, Case No. 177/16.

[*8*] Opinion of Advocate General Wahl delivered on 6 April 2017, *AKKA / LAA*, Case No. 177/16.

[9] CMA, 7 December 2016, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, Case No. CE/9742-13.

[10] CAT, Judgement of 7 June 2018, *Flynn Pharma Ltd and Pfizer Inc. v. CMA*, Case Nos: 1275-1276/1/12/17.

[11] CMA, press release of 21 November 2018.

[12] CMA, press releases of 16 December 2016 and 3 March 2017.

[13] ICA, Decision of 29 September 2016, case No. A480 - INCREMENTO PREZZO FARMACI ASPEN.

[14] 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.

[15] AGCM, Press release of 5 July 2018.

[16] DCC, press release of 31 January 2018.

[17] In Russia for example, the Federal Antimonopoly Service ("**FAS**") recently fined Novartis 912,500 RUB for having abused its position following the imposition of a price increase of 35% on its cancer drug Tyverb (FAS, press release of 12 April 2018). The FAS also recently reached an agreement with AstraZeneca according to which, interestingly, the latter committed to reduce the prices of 11 of its drugs, considered as vital and essential drugs under Russian regulations, between 12 percent and 92 percent, thereby illustrating the thin line between the pursuit of excessive pricing as an anticompetitive behavior and price regulation by competition authorities (FAS, press release of 22 June 2018).

[18] See Opinion of Advocate General Wahl in Case No. 177/16, 6 April 2017. See also M. Motta and A. de Streel, Excessive pricing in competition law: never say never? (2007), published in Konkurrensverket – Swedish Competition Authority (ed.), The Pros and Cons of High Prices, p. 14.

[19] See Concurrences, e-competition bulletin, "*Excessive prices: an overview of EU and national case law*", 21 June 2018;

[20] Commission, Decision of 15 June 2005, affaire COMP/A.37.507/F3 – AstraZeneca.

[21] ICA, Decision of 11 January 2012, case No. A431 – Ratiopharm / Pfizer.

[22] Italian Council of State, Judgment of 12 February 2014, *ICA c. Pfizer*, Case No. 693.

[23] Commission, Decision of 19 June 2013, Case No. AT.39226, Lundbeck; General Court, Judgement of 8 September 2016, *Lundbeck A/S and Lundbeck Ltd v. European Commission*, Case No. T-472/13.

[24] Commission, Decision of 9 July 2014, Case No. AT.39612.

[25] Several hearings took place before the General Court of the European Union between June and July 2017, a judgement is expected in the course of 2018 (Case T-691/14).

[26] CMA, Decision of 12 February 2016, Paroxetine – Case CE-9531/11.

[27] Anatomical Therapeutic Chemical Classification System.

[28] FCA, Decision of 11 May 2013, Case No. 13-D-11 (Sanofi-Aventis) confirmed by Paris Court of Appeal, div. 5 Ch. 5-7, Judgment of 18 December 2014 No. 2013/12370 confirmed by Supreme Court, Commercial Chamber 18 October 2016, Case No. 15-10384. .See also the Subutex case: FCA, Decision of 18 December 2013, Case No. 13-D-21 (Arrow/Scherring-Plough), confirmed by Paris Court of Appeal, div. 5 Ch. 5-7, Judgement of 26 March 2015 No. 2014/0330 and the Supreme Court, Commercial Chamber Judgement of 11 January 2017 No. 15-17134.

[29] FCA, Decision of 20 December 2017, Case No. 17-D-25.

[30] ECJ, Judgement of 23 January 2018, F. Hoffmann-La Roche Ltd e.a./AGCM, Case No. C-179/16.

[31] Hellenic Republic, Competition Commission, Press Release of 11 July 2018.

[32] Application (OJ) C 20 du 27.01.2007 p.3.

[33] ECJ, Judgment of 16 September 2008, *Sot. Lélos Kai Sia*,v. v. *GLAXOSMITHKLINE AEVE*, Case No. C-468/06-478/06.

[34] ECJ, Judgment of 16 September 2008, *Sot. Lélos Kai Sia*,v. v. *GLAXOSMITHKLINE AEVE*, Case No. C-468/06-478/06, §§ 70-77.

[35] FCA, Decisions of 5 July 2007, Case No. 07-D-22 and 13 December 2007, Cases No. 07-D-45 and 07-D-46.