e-Competitions
Antitrust Case Laws e-Bulletin

Concurrences
Antitrust Publications & Events

Pay-for-delay agreements

Pay for delay agreements: An overview of EU and US Case Law

DOMINANCE (ABUSE), INTELLECTUAL PROPERTY, PHARMACEUTICAL, FOREWORD, EUROPEAN UNION, UNITED STATES OF AMERICA, ANTICOMPETITIVE OBJECT / EFFECT, PAY-FOR-DELAY, GENERAL ANTITRUST

Walid Chaiehloudj | University of New-Caledonia

e-Competitions Special Issue Pay-for-delay agreements | 5 May 2021

Are pay-for-delay agreements still a hot topic for competition authorities and courts? The answer, albeit reckless, is definitely "yes". As the years go by, competition authorities still seem determined to fight these agreements, which are sometimes referred to as "patent settlements" or "reverse payment settlements". Fundamentally, there are several reasons why competition authorities on both sides of the Atlantic remain vigilant.

In the United States, the *Actavis* decision of the Supreme Court [*1*], handed down in 2013, did not finally prohibit pharmaceutical companies from concluding pay-for-delay agreements. Strictly speaking, the decision only established that such deals *may* have anticompetitive effects. By rejecting the *per se* rule and by adopting the rule of reason, the Supreme Court did not really put an end to the phenomenon of pay-for-delay. In doing so, it ruled that such agreements could perfectly comply with antitrust law. The Court therefore sent the difficulties back to the lower courts, which are responsible for interpreting the *Actavis* judgment and implementing the "structured rule of reason". This result is far from being satisfactory, because in the absence of a clear doctrine, the message addressed to pharmaceutical companies is extremely ambiguous [2]. The ambiguity is such that pharmaceutical companies are not afraid to enter into pay-for-delay settlements. Furthermore, the FTC's latest report on patent settlements published in 2019 [*3*] reveals that the number of pay-for-delay deals has significantly increased in FY 2016. Compared to 2015, the number of pay-for-delay settlements between brand and generic companies has simply doubled [*4*]. Doesn't this trend express a form of failure in the enforcement of antitrust law in the United States? Maybe it does.

In Europe, the repression of pay-for-delay deals has continued in recent years. At the end of 2020, the European Commission finally handed down its decision in the *Modafinil* case [*5*]. On this occasion, Competition Commissioner, Mme Margrethe Vestager, stated: " *it is illegal if pharmaceutical companies agree to buy-off competition and keep cheaper medicines out of the market. Even when their agreements are in the form of patent settlements or other seemingly normal commercial transactions*". Does this mean that the conclusion of pay-for-delay agreements in Europe is now clearly contrary to Articles 101 and 102 of the TFEU? Absolutely not. Sticking to the Vice-President's [*6*] statement would be misleading. The EU courts, in particular the Court of Justice [7], have recently provided a more nuanced response. To be precise, the Court of Justice opted for a case-by-case approach and refused to put all pay-for-delay deals in the "basket" of the restriction by object. Furthermore, it should be

noted that, as in the United States, pay-for-delay remains a reality in Europe. Pharmaceutical companies continue to enter into agreements with substantial value transfers [*8*] despite the numerous fines imposed by the European Commission in previous years. It is also worth noting that before leaving the EU due to Brexit, the UK gave a final gift to the antitrust community in that the Competition and Markets Authority was able to voice its mistrust of pay-for-delay agreements. In application notably of Article 101 TFEU, the UK authority has fined pharmaceutical companies holding that the agreements concluded had an "anti-competitive object" [*9*]. As a result, Brexit could have an unexpected effect: a differentiated treatment of pay-for-delay agreements in Europe. Because from now on, the judgements of the Court of **J**ustice are no longer binding on the British courts [*10*], and thus also on the UK competition authority.

In this foreword, we will highlight recent developments in the United States and Europe concerning the antitrust assessment of pay-for-delay. The last few years have been particularly rich on both continents. However, the reader should already be warned. Pay-for-delay agreements still remain elusive on both sides of the Atlantic. The latest decisions, while they provide some clarification, they do not shed light on all the grey areas identified by academic doctrine and a number of competition authorities.

I. Pay-for-delay agreements in the United States

In the United States, pay-for-delay has provoked different reactions. On the one hand, legislators have tried to counter the *Actavis* decision (A). On the other hand, the courts have continued their work by handing down decisions which, unfortunately, do not create any consensus (B).

A. Legislative developments

This is perhaps the most striking fact. The legislator is no longer uninterested in pay-for-delay. Primarily, two texts deserve attention. The first has just been enacted in California. This Act is known as Assembly Bill 824 ("AB 824") [*11*]. It considerably weakens the *Actavis* decision. Indeed, the new California law marks a real departure from the "structured rule of reason" established by *Actavis*. How does AB 824 achieve this feat? Simply by rendering certain patent settlements *presumptively* anticompetitive. It should be remembered that the Supreme Court in *Actavis* had abruptly rejected the "quick look" standard [*12*]. California law censors this rejection by making the "quick look rule" the standard to be applied to pay-for-delay agreements [*13*]. According to AB 824, two situations trigger the presumption: if (1) the generic manufacturer obtains "anything of value" from the brand company, including, but not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug, and (2) if the generic manufacturer limits or foregoes research, development, manufacturing, marketing, or sales of the generic medicine for any period of time. In these two cases, AB 824 presumes that the patent settlement was anticompetitive. Above all, the Act shifts the burden from the plaintiffs to the defendants. Now, at least in State of California, it is up to the pharmaceutical companies to rebut the presumption by demonstrating that any value received by the generic manufacturer was a fair compensation for goods or services, or that the settlement generated procompetitive benefits. To sum up, California law lightens the burden of proof in favour of the plaintiffs. As a result, it will be much easier for a plaintiff to obtain the sanction of a pay-for-delay deal in California than in another State where *Actavis* prevails.

Moreover, the Californian legislator wanted to curb the phenomenon of pay-for-delay by introducing highly dissuasive penalties. The new law foresees two alternative sanctions taking the form of civil penalties. Concretely, the State of California can obtain civil penalties from each of the brand and generic manufacturer of up to three times the value of the alleged payment based on California's share of sales in the medicine, or $20 million, whichever is greater.

The second text has not yet been adopted. It has a much wider scope than AB 824 in the sense that it is not circumscribed to a single State. The bill is also more radical. Indeed, in May 2019, the U.S. House of Representatives passed a health care bill that included provisions to prohibit pay-for-delay settlements [*14*]. The aim here is not to relax the *Actavis* decision. It is simply to bury the decision. The bill would create a "rebuttable presumption of illegality" for any pay-for-delay settlement involving a value transfer to a generic or biosimilar company in return for its agreement to "limit or forego" efforts to develop, manufacture, market or sell the generic medicine. In short, if the bill were adopted, it would establish a *per se* rule and thus prohibit purely and simply pay-for-delay agreements in United States. Would the legislator be taking the right path by adopting a principle of prohibition? Possibly not. Pay-for-delay is not a mere commercial agreement. The size of the payment is not always a sign of anticompetitive behaviour. A large payment may simply terminate a long and expensive patent dispute or compensate services provided by generic companies. With this in mind, is it reasonable to establish a general prohibition rule and forget about the patent context?

B. Controversial decisions

Although frankly contested by some legislations, the *Actavis* judgment remains in force. The FTC and the courts are in charge of its interpretation and its enforcement. In recent years, the most interesting case is the *Impax* case [*15*]. For the first time, the FTC has had to apply the principles set out in *Actavis*. From the outset, it must be said that the FTC interpreted the decision very strictly! This decision has in fact generated a great controversy to such an extent that the Association for Accessible Medicines (AAM), a generic industry lobby, has weighed in to try to overturn the FTC's ruling against *Impax [16]*. But what is the problem?

The main problem is that the *Impax* decision over-interprets the *Actavis* judgment. Originally, *Actavis* seems to be aimed simply at pay-for-delay agreements containing cash payments [*17*]. However, in the *Impax* case, the consideration for withdrawing the commercialization of the generic was not millions of dollars. Rather, it was a "non-monetary payment" taking the form of a commitment not to launch authorized generics on the market [*18*]. In addition, the settlement allowed *Impax* to enter on the market ten years earlier than otherwise possible and eight months before expiration of Endo's original patent monopoly. Wasn't this pro-competitive justification enough to save the settlement? Aren't consumers better off when the generic medicine enters the market before the end of patent protection?

This over-interpretation of the *Actavis* judgment by FTC seems to lead to an impasse. A patent settlement is only possible if the parties make reciprocal concessions. If the parties were deprived of both non-monetary and monetary payments, what would be left for the originator companies to negotiate the end of the patent dispute? Anyway, the case has been referred to the Fifth Circuit Court of Appeals. It will be interesting to see whether the FTC's position has been convincing. If the FTC prevails, it would seem, at first sight, to be the end of the pay-for-delay settlements, at least for a large part of them. However, in fact, arguing that the FTC's victory would mark the end of pay-for-delay would be partly untrue. For years, practitioners have been adapting to find less sensitive considerations (e.g. non-cash payments have gradually substituted cash payments in many settlements). No doubt they will find a way to keep settlements attractive and in line with case law. The imagination of lawyers is huge. Therefore, we should not underestimate the possible appearance of new pay-for-delay settlements subtler than the old ones.

Ultimately, the antitrust assessment has not yet stabilized in the United States. In the hypothesis where several courts would divide, a new intervention of the Supreme Court cannot be excluded. The *Actavis* ruling has in fact not resolved the problem of pay-for-delay agreements. Saying that the agreements *may* have anticompetitive effects

seems insufficient. Nor is the 'structured rule of reason' any more convincing. This rule of reason does not take sufficient account of the fact that pharmaceutical companies hold patents and that some of them are not necessarily weak patents.

II. Pay-for-delay agreements in Europe

In Europe, the year 2020 is not only the year of the Digital Market Act. It is also the year of pay-for-delay. The Covid-19 pandemic has not prevented the Commission from doing its job. Once again, the Commission reiterated that it considered pay-for-delay agreements as anticompetitive. Indeed, in the *Modafinil* case, the Commission handed down a decision sanctioning for the fourth time this type of agreement. According to the Commission, pay-for-delay are nothing more than vulgar agreements aimed at sharing markets [*19*]. To date, the Commission has still not published its decision. Therefore, it is difficult to comment its reasoning. Actually, the most important decision in 2020 is the *Generics* judgment pronounced by the Court of Justice at the very beginning of this year. This preliminary ruling provides valuable information on the antitrust assessment to be applied to pay-for-delay agreements. Although interesting, the decision, however, is not entirely satisfactory. The judgment oscillates between uncertainty and clarification. First of all, uncertainties remain regarding the application of Article 101 TFEU (A). Secondly, clarifications have been made regarding the application of Article 102 TFEU (B).

A. Uncertainties regarding the application of Article 101 TFEU

By object or by effect? The answer is still unclear. It is well known that the European Commission favours restriction by object and that its reasoning has been supported by two rulings of the General Court in the *Lundbeck* [*20*] and *Servier cases* [*21*]

What does the Court of Justice think about this critical issue?

In its preliminary judgment, the Court provides a very balanced framework for the analysis of pay-for-delay agreements in EU competition law. Precisely, the Court does not evade the intellectual property context. It seems to have understood that pay-for-delay settlements are often implemented in a context of patent uncertainty. From this perspective, the Court delivered a compromise judgment.

First, the Court has a very generous view of potential competition, very favourable to the claimants and the competition authorities. The threshold required to establish potential competition is very low. Indeed, the Court tolerates indirect indicia such as an applying for an administrative authorization for the marketing of a generic version of the medicine concerned or the situation where a generic company holds an adequate stock of that generic medicine either through its own production or through supply contracts concluded with third parties [*22*]. Then, according to the Court, it is necessary to consider whether there are insurmountable barriers to entry that prevent the generic company from bringing its generic medicine to market. In this respect, the Court states that '*the existence of a patent which protects the manufacturing process of an active ingredient that is in the public domain cannot, as such, be regarded as an insurmountable barrier, and does not mean that a manufacturer of generic medicines who has in fact a firm intention and an inherent ability to enter the market, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being subject to infringement proceedings brought by the patent holder, cannot be characterized as a 'potential competitor' of the manufacturer of originator medicines concerned*' [*23*]. In other words, it must be understood that each time the patent on the molecule is in the public domain, potential competition will certainly be demonstrated. All settlements based on a secondary patent therefore become suspect.

Second, the Court holds that a pay-for-delay settlement does not amount to a restriction of competition by object in all circumstances. The idea is as follows: the restriction of competition by object is not systematic. In order to deduce that the settlement is anticompetitive by object, an enquiry must be carried out. Concretely, a competition authority (or a claimant in the context of private enforcement) would need to show that the settlement is a means to "deliberately substitute practical cooperation between them for the risks of competition". What does this mean? Simply that the patent settlement has an anticompetitive object when it has been concluded only to impede competition. In fact, this principle sounds almost impracticable. Because it is very difficult to determine the intention of the parties in a patent dispute context. Consequently, legal uncertainty continues to be very significant for companies as it is still difficult to separate good settlements from bad ones. The fog is all the greater inasmuch as the Court notes that "*it cannot be asserted that the conclusion of such an agreement represents, on the part of the manufacturers of generic medicines, no more than their recognition of patent rights, presumed to be valid, of the holder of that patent*" [*24*]. Almost all patent settlements are concluded with this justification. Is it therefore to be understood that the object restriction can only be used in the future in very caricatured circumstances? In other words, should it be considered that only pay-for-delay with disproportionately large compensation should be included in the "object box"? Nothing is less certain. Perhaps this principle should be read in the light of a subsequent judgment. In *Budapest Bank* [*25*], the Court provided an important clarification. In its ruling, the Court stated that "*in order to justify an agreement being classified as a restriction of competition 'by object', without an analysis of its effects being required, there must be sufficiently reliable and robust experience for the view to be taken that that agreement is, by its very nature, harmful to the proper functioning of competition*" [*26*]. In the light of this judgment, it must be understood that if there is insufficient experience about the nature, purpose and potential (pro- and anticompetitive) effects of a pay-for-delay settlement, a claimant or authority would not be in a position to show that it is restrictive by object. But, on the one hand, there is no significant experience with pay-for-delay, and on the other hand, uncertainty is inherent in these settlements for the reason that the disputed patents are presumed to be valid…

In short, it seems that the door is wide open for "restriction by effect". However, the Court does not state this clearly. As a result, it is still impossible to know whether or not a pay-for-delay settlement complies with Article 101 TFEU at the time of its conclusion.

B. Clarifications regarding the application of Article 102 TFUE

Generics offers much more concerning the abuse of a dominance. The *Servier* judgment of the General Court, handed down in 2018, might have suggested that abuse of a dominant position would be difficult to mobilise against pay-for-delay. In that case, the General Court had partially censured the Commission's reasoning which had made a series of errors in the defining the relevant market. The General Court holds that the Commission, *inter alia*, wrongly considered that the product under consideration, *perindopril*, differed, in terms of therapeutic use, from other ACE inhibitors, while underestimating the propensity of patients treated with *perindopril* to change medicines and attributed excessive importance to the price factor in analysing the competitive constraints. Consequently, it could only be concluded that *Servier* did not hold a dominant position.

However, the *Generics* judgment shows that the abuse of a dominant position remains a possible way to sanction the pay-for-delay practice. Of course, the prerequisite is always to determine the existence of a dominant position. In this regard, there is no doubt that the Commission will be more vigilant with regard to the *Servier* case. But it is primarily on the second stage, i.e. the characterization of the abuse, that the *Generics* judgment provides important clarifications. Yes, the conclusion of pay-for-delay settlements may infringe Article 102 TFEU. This is how the judgment could be summarized. In reaching this conclusion, the Court appears to have transposed the "theory of cumulative effect" to Article 102 TFUE. This theory, developed for the application of vertical agreements under

Article 101 TFEU [27], seems entirely appropriate. Indeed, the Court rules that the conclusion of "a set" of pay-for-delay agreements may have anticompetitive effects [28]. However, the Court of Justice does not condemn such conduct *per se*. It is necessary to show that the conclusion of the set of settlements has produced anticompetitive effects on the market. It is true that, taken individually, a settlement could produce no anticompetitive effect from an Article 102 perspective. This is certainly not the case when several identical settlements are concluded with different generic companies. In such a case, the market could be entirely blocked. However, the Court recalls that the defendant company will always be able to demonstrate that its conduct has pro-competitive effects. The Court reminds that a company in a dominant position may justify its conduct by efficiency gains, in line with the *Post Danmark* [29] judgment. The assessment presupposes a balancing of positive and negative effects on competition.

A few years ago, when we defended our thesis [30], we insisted that "pay-for-delay" agreements are primarily a patent problem not an antitrust one. As the years go by, we can argue that this intuition could be right. How else to explain the current impasse? Perhaps we have simply to accept that competition law may not be the appropriate solution to resolve this issue. *Errare humanum est, perseverare diabolicum…*

See also Walid Chaiehloudj, Les Accords de Report d'Entrée, Concurrences, 2019

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 FTC v. Actavis, Inc., 570 U.S. 136 (2013) ; *Joshua D. Wright, FTC v. Actavis and the future of reverse payment cases, December 2013, Concurrences N° 4-2013, Art. N° 59202.*

[2]] However, some authors continue to read the *Actavis* decision as a victory of the FTC over pharmaceutical companies. See for example: *Michael A. Carrier, Pharmaceutical antitrust: What the Biden administration can do, February 2021, Concurrences N° 1-2021, Art. N° 98407.*

[3]] FTC, Bureau of Competition, Agreements filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements filed in FY 2016 (2019) [hereinafter FTC, FY 2016 Report].

[4]] FTC, FY 2016 Report, *supra* note 3, p. 4. In 2015, 14 pay-for-delay deals were concluded. In 2016, the number of agreements reached 30.

[5]] See *Teva and Cephalon, Case AT.39686, November 26, 2020* ; *Peter L'Ecluse, Catherine Longeval, Koen T'Syen, The EU Commission fines two pharmaceutical companies for "pay-for- delay" patent settlement agreement (Cephalon / Teva), 26 November 2020, e-Competitions Pay- for-delay agreements, Art. N° 98080* ; *Duncan Liddell, Steven Vaz, The EU Commission fines pharmaceutical companies for pay-for-delay agreement (Teva / Cephalon), 26 November 2020, e- Competitions Pay-for-delay agreements, Art. N° 98232* ; *European Commission, The EU*

Commission fines 2 pharmaceutical companies €60.5 million for delaying the entry of cheaper generic medicine for sleep disorders (Teva / Cephalon), 26 November 2020, e-Competitions Pay-for-delay agreements, Art. N° 98256.

[6]] Mme Vestager is also Vice-President of the European Commission.

[7]] See *Generics (UK) Ltd and others v Competition and Markets Authority*, Case C-307/18 [2020], EU:C:2020:52, [hereafter Generics] ; *Alain Ronzano, Pay for delay: Advocate General Kokott invites the Court to rule that an Pay for Delay agreement may constitute a restriction of competition by object or effect and that its conclusion may be analysed as an abuse of a dominant position (Generics - UK), 22 January 2020, Concurrences N° 2-2020, Art. N° 93030* ; *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), 30 January 2020, e-Competitions January 2020, Art. N° 93498* ; *Catriona Hatton, Paul Lugard, Daniel Vasbeck , The EU Court of Justice clarifies for the first time when patent settlement agreements that restrict a generic pharmaceutical company's ability to enter the market infringe the EU antitrust rules (Generics - UK), 30 January 2020, e-Competitions January 2020, Art. N° 93745* ; *Donald Slater , The EU Court of Justice clarifies the conditions for a pay-for-delay agreement to be qualified as a restriction of competition by object (Generics - UK / GlaxoSmithKline / Actavis / Xellia Pharmaceuticals / Merck / Alpharma), 30 January 2020, e-Competitions January 2020, Art. N° 95834* ; *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), 30 January 2020, e-Competitions January 2020, Art. N° 94657.*

[8]] EU Commission, *8th Report on the Monitoring of Patent Settlements (period: January-December 2016),* Published on 9 March 2018, p. 13. The report indicates that, in the period investigated, agreements with value transfers accounted for 11% (12 out of 107) of all agreements.

[9]] See *UK Competition and Markets Authority, Aspen / Tiofarma / Amilco*, Case 50455, July 9, 2020 ; *UK Competition Authority, The UK Competition Authority fines 3 pharmaceutical companies £2.3 million for anti-competitive agreement in the supply of life-saving drug fludrocortisone and secures £8 million in damages for the National Health Service (Aspen / Tiofarma / Amilco), 9 July 2020, e-Competitions July 2020, Art. N° 95771.*

[10]] However, "*in accordance with the terms of the withdrawal agreement, the Court of Justice is to continue to have jurisdiction in any proceedings brought by or against the UK before the end of the transition period, which is set as 31 December 2020. It is also to continue to have jurisdiction to give preliminary rulings on requests from courts and tribunals of the UK made before the end of the transition period*". See Court of Justice, Consequences of the United Kingdom's withdrawal from the European Union for the Court of Justice of the European Union, Press Release, January 31, 2020.

[11]] This Act was enacted on October 7, 2019.

[12]] As Professor Piraino pointed out, "*the quick look is an abbreviated form of analysis similar to the per se rule*". See T.A Piraino, The Antitrust Analysis of Joint Ventures After the Supreme Court's Dagher Decision, 57 Emory L. J. 735 (2008).

[13]] Here, the legislator has implicitly relied on well known decision of the Supreme Court. In

California Dental Association v. FTC, the Supreme Court indicates the assumption that the application of the "quick look rule" is appropriate: "*An abbreviated or 'quick-look' analysis is appropriate when an observer with even a rudimentary understanding of economics could conclude that the arrangements in question have an anticompetitive effect on customers and markets*". See *California Dental Association v. FTC*, 526 U.S. 756 (1999).

[14]] Other bills have been introduced in Congress. For more information, see for example L. Karas, G. F. Anderson ; R. Feldman, Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?, 71 *Hastings L. J.* 959 (2020).

[15]] See *FTC, Commissioner Opinion, Impax,* March 28, 2019 ; *Michael A. Carrier, The U.S. FTC reverses Administrative Law Judge decision, finding Section 5 violation for reverse-payment settlement (Impax), 28 March 2019, e-Competitions March 2019, Art. N° 90331* ; *Katie R. Beran, Melinda R. Coolidge, The US FTC concludes that a pharma company entered into an illegal pay-for-delay agreement (Impax), 28 March 2019, e-CompetitionsMarch 2019, Art. N° 96409* ; *Walid Chaiehloudj, United States: The Federal Trade Commission rules that two pharmaceutical laboratories concluded an unlawful pay-for-delay agreement (Impax Laboratories), 28 March 2019, Concurrences N° 2-2019, Art. N° 90539.*

[16]] Brief of the Association for Accessible Medicines as Amicus Curiae in Support of Respondent, *Impax Labs., Inc. v. FTC* (5th Cir. filed Oct. 10, 2019).

[17]] Already in the past, some courts had made this interpretation. See for example: *In re Lamictal Direct Purchaser Antitrust Litig*., 18 F. Supp. 3d 560, 562 (D.N.J. 2014): "*nothing in Actavis says" that "a no-AG agreement is a 'payment'" or that "a settlement [agreement] contains a reverse payment when it confers substantial financial benefits*." ; *Nicole Daniel, The U.S. FTC files an amicus brief in the Court of Appeals explaining that commitment not to compete raises the same antitrust concerns as the reverse-payment patent settlements (King Drug / SmithKlineBeecham), 28 April 2014, e-Competitions April 2014, Art. N° 66851.*

[18]] An authorized generic is approved by the FDA as brand drugs but marketed as generic by brand companies.

[19]] Already in 2014, the Commission had clearly taken the part of this qualification. See Commission Staff Working Document – Guidance on restrictions of competition 'by object' for the purpose of defining which agreements may benefit from the *De Minimis* Notice, SWD(2014) 198 final, June 25, 2014, p. 8: "*An agreement whereby a competitor pays a significant amount to an actual (or potential) competitor to stay out of a particular market was considered to be a form of market sharing"*.

[20]] See Case T-472/13, *H. Lundbeck A/S v European Commission* [2016], EU:T:2016:449 ; *Alain Ronzano, Pay for delay : The General Court of the European Union confirms the Commission's approach (Lundbeck), 8 September 2016, Concurrences N° 4-2016, Art. N° 82207* ; *Louise Aberg, The EU General Court confirms fines imposed on an undertaking and generic drug manufacturers for entering into anticompetitive "pay-for-delay" agreements (Lundbeck), 8 September 2016, e-Competitions September 2016, Art. N° 92780* ; *Gabriele Accardo, Anthony Reda, The EU Commission fines pharmaceutical companies for delaying market entry of generic medicines (Lundbeck), 19 June 2013, e-Competitions June 2013, Art. N° 57743* ; *European Competition Network Brief, The EU Commission fines pharmaceutical companies for delaying market entry of generic medicines through pay-for-delay agreements (Lundbeck), 19 June 2013, e-Competitions June 2013, Art. N° 53279.*

[21]] See Case T691/14, *Servier SAS v European Commission* [2018], EU:T:2018:922 ; *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 Pay-for-delay agreements, Art. N° 90103* ; *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 Pay-for-delay agreements, Art. N° 94166* ; *Peter L'Ecluse, The EU General Court offers a mixed review of patent settlement agreements in the pharmaceutical sector (Servier), 12 December 2018, e-Competitions Pay-for-delay agreements, Art. N° 88976* ; *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 Pay-for-delay agreements, Art. N° 88946.*

[22]] *Generics*, para 44.

[23]] *Ibid.,* para 46.

[24]] *Ibid.,* para 89.

[25]] See Case C-228/18, *Gazdasági Versenyhivatal v Budapest Bank Nyrt. and Others* [2020], EU:C:2020:265 ; *Alain Ronzano, Object restriction: The Court of Justice of the European Union calls on the Hungarian Supreme Court to ascertain whether the multilateral interchange fee set by the banks for credit card transactions with a merchant pursued no objective other than a simple price increase (Gazdasági Versenyhivatal / Budapest Bank), 2 April 2020, Concurrences N° 3-2020, Art. N° 94073* ; *Michel Debroux, Restriction of competition by object: The Court of Justice of the European Union once again attempts to clarify the concept of restriction of competition "by object" (and does not fully succeed) and to provide a pragmatic methodology to identify such restrictions (and does not fully fail) (Gazdasági Versenyhivatal / Budapest Bank Nyrt), 2 April 2020, Concurrences N° 3-2020, Art. N° 96143* ; *Yves Botteman, Camille Keres , The EU Advocate General Bobek publishes his opinion on the concept of restriction of competition by object or by effect (Gazdasági Versenyhivatal / Budapest Bank), 5 September 2019, e-Competitions September 2019, Art. N° 92036* ; *Simon Troch, Daphné Van der Eycken, The Advocate General Bobek provides an analytical framework to assess the appropriateness of 'by object' qualifications while clarifying and consolidating the case-law on the dichotomy between 'by object' and 'by effect' restrictions (Budapest Bank), 5 September 2019, e-Competitions September 2019, Art. N° 92640* ; *Richard Burton, The EU Court of Justice ascertains whether the multilateral interchange fee set by the banks for credit card transactions with a merchant pursued no objective other than a simple price increase (Budapest Bank), 2 April 2020, e-Competitions April 2020, Art. N° 94727.*

[26]] *Ibid.,* para 76.

[27]] See Case C-234/89, *Delimitis* [1991], EU:C:1991:91.

[28]] *Generics*, para 172.

[29]] See Case C209/10, *Post Danmark [2012*], EU:C:2012:172 ; *Wessel Geursen, The EU Court of Justice endorses an effects-based approach on the assessment of low pricing policy under Article 102 TFEU (Post Danmark), 27 March 2012, e-Competitions March 2012, Art. N° 57395*

; *Anne-Lise Sibony, Selective rebates – Universal service obligations: The Court of Justice, Grand Chamber, rules that selective rebates targeting clients of a competitor are not abusive when prices are below incremental cost but cover marginal cost and when no intent to eliminate competitor has been established (Post Danmark), 27 March 2012, Concurrences N° 2-2012, Art. N° 45619* ; *Damien Gerard , The EU Court of Justice applies the effects-based approach to claim of exclusionary pricing abuse (Post Danmark), 27 March 2012, e-Competitions March 2012, Art. N° 54030* ; *Alain Ronzano, Selective prices: The EU Court of Justice confirms the implementation of the Akzo/Deutsche Post test to selective prices practices by a dominant operator having an obligation to provide universal service (Post Danmark), 27 March 2012, Concurrences N° 2-2012, Art. N° 55527* ; *Lucas Peeperkorn, The EU Court of Justice affirms the application of a consumer-oriented effects-based approach to exclusionary pricing practices of dominant undertakings and the "as efficient competitor test" (Post Danmark), 27 March 2012, e-Competitions March 2012, Art. N° 48816*.

[30]] See W. Chaiehloudj, *Les accords de report d'entrée – Contribution à la relation du droit de la concurrence et du droit des brevets*, Concurrences, 2019 (in French) ; *Perrine Perez , Les accords de report d'entrée. Contribution à l'étude de la relation du droit de la concurrence et du droit des brevets, Walid CHAIEHLOUDJ, September 2018, Concurrences N° 3-2018, Art. N° 87439*.